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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) of Regulation (EC) No. 726/2004

Chapter 3.II: XEVPRM User Guidance

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Summary of changes

Following the publication of version 3.13 on 26 July 2018 the content of the below listed sections was amended. The changes are highlighted in red and strikethrough text.

- NOTE 2
- 1.2.12.2. Authorisation procedure (AP.12.2)
- NOTE 3
- 1.2.12.13. Legal basis (AP.12.13)
- NOTE 6
- 1.6.10. Country Code (O.10)

Please note that editorial changes of this document are not included in the summary of changes.

Introduction

This document provides user guidance on:

- the data elements to be completed for the electronic submission of information on medicinal products for human use **authorised** in the European Economic Area (EEA) using the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM);
- the maintenance of medicinal product data previously submitted.

The data elements for medicinal products are based on the following reference information:

- Summary of Product Characteristics (SmPC), which serves the purpose of validation of the information provided in the structured data elements:
 - Section 1. Name of the medicinal product,
 - Section 2. Qualitative and quantitative composition,
 - Section 3. Pharmaceutical Form,
 - Section 4.1 Therapeutic indications,
 - Section 4.2 Posology and method of administration,
 - Section 5.1 Pharmacodynamic properties,
 - Section 6.1 List of excipients,
 - Section 6.5 Nature and contents of container,
 - Section 7. Marketing Authorisation Holder,
 - Section 8. Marketing Authorisation Number,
 - Section 9. Date of first authorisation/renewal of the authorisation,
 - Section 10. Date of revision of the text;
- Medicinal product authorisation information (as referred to in the [Legal Notice on the Implementation of Article 57\(2\) of Regulation \(EC\) No. 726/2004](#) published by the Agency);
- Pharmacovigilance information (as referred to in the [Legal Notice on the Implementation of Article 57\(2\) of Regulation \(EC\) No. 726/2004](#) published by the Agency).

All medicinal product names/marketing authorisation holder names used in this document are fictitious and were created for the purposes of being used as examples in this user guidance.

Background information

New pharmacovigilance legislation ([Regulation \(EU\) No 1235/2010](#) amending [Regulation \(EC\) No 726/2004](#) and [Directive 2010/84/EU](#) amending [Directive 2001/83/EC](#)) was adopted by the European Parliament and European Council in December 2010. The legislation is the biggest change to the regulation of human medicines in the European Union (EU) since 1995. It has significant implications for applicants and holders of EU marketing authorisations. The European Medicines Agency is responsible for implementing much of the new legislation and developed a framework for compliance and delivery of key requirements. The legislation applies from July 2012.

One of the key deliverables of the new legislation relates to the submission of medicinal product information by marketing authorisation holders to the European Medicines Agency. Article 57(2) of Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012, requires:

- *the Agency to publish the format for the electronic submission of information on medicinal products for human use by 2 July 2011;*
- *marketing authorisation holders to submit information to the Agency electronically on all medicinal products for human use authorised in the European Union by 2 July 2012, using this format;*
- *marketing authorisation holders to inform the Agency of any new or varied marketing authorisations granted in the EU as of 2 July 2012, using this format.*

Marketing authorisation holders are also required to submit information concerning all medicinal products for which they hold a marketing authorisation in EEA countries outside the EU (i.e. Iceland, Liechtenstein and Norway), as the pharmacovigilance legislation has been incorporated into the EEA Agreement and entered into force in the EEA on 28 May 2014.

Medicinal products falling **out of scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligations** include:

- investigational medicinal products;
- products for which the marketing authorisation is not valid;
- traditional use registration application for herbal medicinal products (Article 16a of Directive No 2001/83/EC)¹;
- simplified registration application for a homeopathic medicinal products (Article 14 of Directive No 2001/83/EC)¹;
- medicinal products within the scope of Article 5 of Directive 2001/83/EC i.e. 'Named patient use' falling under Article 5(1) and 'EU Distribution Procedure' under Article 5(2);
- parallel Distributed/Imported medicinal products (Article 76(3) and (4) of Directive No 2001/83/EC);
- medicinal products authorised outside the EEA or following a non-EU procedure.

Medicinal products falling out of scope of Article 57(2) legal obligation may be submitted on voluntary basis in line with the requirements and business processes described in this guidance.

¹ See also [Note for clarification: Traditional herbal medicinal product and simplified registration for homeopathic medicinal products: pharmacovigilance requirements and EudraVigilance access](#) for related information

Medicinal product data shall be submitted to the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) using the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM). For more information please see the below listed document:

- [Chapter 2: Electronic submission of information on medicinal products by marketing authorisation holders](#) and [Chapter 3.I: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#) of the published *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) of Regulation (EC) No. 726/2004* published at the [Agency's website](#) for detailed information on the XEVPRM structure and the applicable business rules can be found in.

Available operation types to be used in an XEVPRM

- Operation type '**Insert**' (1): allows the sender organisation to insert medicinal product information in the XEVMPD.

For EVWEB users, a command button '**Reinsert**' (1) is also available. This operation type allows EVWEB users to re-insert an existing medicinal product whilst retaining the previous information and create a new medicinal product with the operation type 'Insert'.

- Operation type '**Update**' (2): allows the sender organisation to correct erroneous information previously submitted.

As per specific guidance provided in section [2. Maintenance of medicinal product data](#) of this document, this operation type shall be used to maintain some of the medicinal product information.

- Operation type '**Variation**' (3): *This operation type is no longer available as it should not be used to notify the Agency of a variation procedure of an authorised medicinal product in the context of maintenance of medicinal product data during the transition maintenance phase. As of 16 June 2014, the "Variation" button is removed from the EVWEB application. Gateway users, who will submit an XEVPRM containing an authorised medicinal product assigned with operation type 'Variation' (3) will receive a negative XEVPRM acknowledgement as the entire XEVPRM will be rejected.*

The process to be followed to amend an authorised medicinal product entity following a variation procedure is described in section [2.4.1. Variations of marketing authorisation](#) of this document.

- Operation type '**Nullification**' (4): allows users to flag incorrectly submitted information (including duplicated information) as 'non-current'.
- Operation type '**Change ownership**' (5): This operation type is no longer available.

The relevant processes to be followed to amend an authorised medicinal product entity following a transfer of marketing authorisation are described in section [2.4.3. Transfer of marketing authorisation](#) of this document.

- Operation type '**Invalidate MA**' (6): This operation allows the sender organisation to submit a notification about the withdrawal of an authorised medicinal product from the market in an XEVPRM. The 'Invalidate MA' operation covers a number of scenarios including the transfer of an authorised medicinal product to a third party and a renewal of the marketing authorisation (MA) by the marketing authorisation holder (MAH) if the marketing authorisation number changes.

Further information on specific scenarios where such operation can be used is provided in section [2. Maintenance of medicinal product data](#) of this document.

Following a successful submission of new medicinal product data, an EV Code is assigned to each XEVMPD entity (i.e. data element). The EV Code is provided to the marketing authorisation holder sender organisation in an eXtended EudraVigilance Medicinal Product Report Message Acknowledgement (XEVPRM_ACK):

- users from MAH organisations submitting XEVPRMs in EVWEB can retrieve the XEVPRM ACK in their WEB Trader Inbox (or Archived Inbox),
- Gateway users should check with their Gateway provider where the XEVPRM ACKs are stored.

For more information please see also:

- [Chapter 5: Extended EudraVigilance product report acknowledgement message](#) and [Chapter 3.I: Extended EudraVigilance product report message \(XEVPRM\) technical specifications](#) of the published 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) of Regulation (EC) No. 726/2004 published on the [Agency's website](#) for detailed information related to an XEVPRM Acknowledgements.
- List of [XEVMPD Element Acknowledgement Codes](#) can be found on the [Agency's 'Guidance documents' webpage](#).

1. Initial submission of medicinal product data

1.1. Initial submission of an authorised medicinal product (AMP) entity

Authorised medicinal product (AMP) must be submitted in the XEVMPD in an XEVPRM with operation type 'Insert' (1).

In accordance with point (b) of Article 57(2) of Regulation (EC) 726/2004: *"marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the European Medicines Agency (the Agency) information on all medicinal products for human use authorised in the European Union, using the format referred to in point (a)".* This includes centrally authorised medicinal products.

In accordance with the Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004, information on medicinal products for new marketing authorisations in the Union after 2 July 2012 shall be submitted by marketing authorisation holders electronically to the Agency as soon as possible and no later than **15 calendar days** from the date of authorisation (i.e. 15 calendar days from the date of notification of the granting of the marketing authorisation by the competent authority).

Regulatory processes for issuing marketing authorisations and authorisation numbers for medicinal products can differ depending on the country of authorisation or the authorisation procedure. This has been recognised as a challenge for the unique identification of medicinal products. The future use of the ISO IDMP standards will allow for the assignment of additional identifiers as an indexing mechanism, which can be applied supplementary to existing systems like the assignment of marketing authorisation numbers.

Medicinal products are being characterised as part of the initial XEVPRM submissions based on the main following characteristics:

- a) Name of the medicinal product
- b) Marketing authorisation holder
- c) Marketing authorisation number
- d) Authorising body (i.e. Competent Authority)
- e) Qualitative and quantitative composition (ingredients, strength, authorised/administrable pharmaceutical form)

Whenever any of the characteristics described above (point a. to e.) for a medicinal product are different, a separate medicinal product entity should be submitted in the XEVMPD. This also applies to medicinal products for which one marketing authorisation has been issued with the same marketing authorisation number.

For centrally authorised medicinal products, separate authorisation numbers (EU numbers) exists for each medicinal product and package presentation. Therefore, for each presentation (each EU number) a separate medicinal product entity should be submitted to the XEVMPD (see *EXAMPLE 5*).

EXAMPLE 1

In Ireland, a marketing authorisation has been granted for 'Diclofenac 50 mg' formulation.

The marketing authorisation number is: PL 1234/000.
The marketing authorisation holder is company MAH-AZ.

The marketing authorisation refers to the following medicinal products names, i.e. the following names listed in section 1 of the SmPC are:

'Diclofenac PharmaB 50 mg tablets'
'Diclofenac tablets'
'Diclofenac 50 mg'

Based on the principles outlined above (different medicinal product names), the marketing authorisation holder should submit three separate medicinal product entries to the XEVMPD:

AMP entity 1: "Full Presentation Name" (AP.13.1) = Diclofenac PharmaB 50 mg tablets
AMP entity 2: "Full Presentation Name" (AP.13.1) = Diclofenac tablets
AMP entity 3: "Full Presentation Name" (AP.13.1) = Diclofenac 50 mg

EXAMPLE 2

In Ireland, marketing authorisation has been granted for the medicinal product 'Amoxicillin 200 mg tablets'.

The medicinal product is available in the following pack sizes: 15 tablets, 30 tablets.

The marketing authorisation number applicable to both pack sizes is PL 1234/001.

The marketing authorisation holder is company MAH-XYZ.

Based on the principles outlined above (the package quantity is not one of the criteria that is normally required for a separate medicinal product entity for non-centrally authorised medicinal products to be created in the XEVMPD), the marketing authorisation holder can submit one medicinal product entity to the XEVMPD (see Option 1).

It is also acceptable for marketing authorisation holders to submit one separate medicinal product for each package presentation for non-centrally authorised medicinal products, where more than one package presentation is covered by one marketing authorisation number. In such case, two medicinal product entries should be submitted to the XEVMPD, each containing different package size in the 'Package Description' field (see Option 2).

Please note that mandatory provision of pack size information and the information on the product down to the pack size level have been deferred to until ISO IDMP standards implementation. Therefore, if Option 1 is selected, a major resubmission will need to be performed when ISO IDMP standards will be implemented.

Option 1

AMP entity 1:

"Full Presentation Name" (AP.13.1) = Amoxicillin 200 mg tablets
"Authorisation Number" (AP.12.4) = PL 1234/001
"Package Description" (AP.13.7) = 15 tablets, 30 tablets

Option 2

AMP entity 1:

"Full Presentation Name" (AP.13.1) = Amoxicillin 200 mg tablets

"Authorisation Number" (AP.12.4) = PL 1234/001
"Package Description" (AP.13.7) = 15 tablets

AMP entity 2:

"Full Presentation Name" (AP.13.1) = Amoxicillin 200 mg tablets
"Authorisation Number" (AP.12.4) = PL 1234/001
"Package Description" (AP.13.7) = 30 tablets

EXAMPLE 3

In France, marketing authorisation has been granted for the medicinal product 'Paracétamol 150 mg comprimés'.

The medicinal product is available in the following pack sizes: 30 tablets and 60 tablets.

The marketing authorisation number applicable: 123 456-7 (30 tablets), 123 456-8 (60 tablets).

The marketing authorisation holder is company MAH-XYZ.

Based on the principles outlined above (different authorisation number for each pack size), the marketing authorisation holder should submit two medicinal product entries to the XEVMPD:

AMP entity 1:

"Full Presentation Name" (AP.13.1) = Paracétamol 150 mg comprimés
"Authorisation Number" (AP.12.4) = 123 456-7
"Package Description" (AP.13.7) = 30 comprimés

AMP entity 2:

"Full Presentation Name" (AP.13.1) = Paracétamol 150 mg comprimés
"Authorisation Number" (AP.12.4) = 123 456-8
"Package Description" (AP.13.7) = 60 comprimés

EXAMPLE 4

In the Ireland, marketing authorisation has been granted for the medicinal product 'Ibuprofen 250 mg'. The medicinal product is available as film-coated tablets and capsules in separate package presentations.

The marketing authorisation number applicable for both medicinal products: PL 1234/004.

The marketing authorisation holder is company MAH-XYZ.

Based on the principles outlined above (different pharmaceutical forms), the marketing authorisation holder should submit two medicinal product entries to the XEVMPD:

AMP entity 1 (film-coated tablet):

"Full Presentation Name" (AP.13.1) = Ibuprofen 250 mg
"Authorisation Number" (AP.12.4) = PL 1234/004
"Pharmaceutical form" = Film-coated tablet

AMP entity 2 (capsule):

"Full Presentation Name" (AP.13.1) = Ibuprofen 250 mg
"Authorisation Number" (AP.12.4) = PL 1234/004

Pharmaceutical form = Capsule

EXAMPLE 5

In the EU, marketing authorisation has been granted for the medicinal product 'COMET'.
The medicinal product is available as 10 mg and 40 mg tablets in the same package presentation.
The marketing authorisation number is: EU/1/13/999/001.
The marketing authorisation holder is company MAH-ABC.
Section 1. Name of the medicinal product states of the SmPC states:

COMET 10 mg tablets

COMET 40 mg tablets

The marketing authorisation holder should submit one medicinal product entity with the two pharmaceutical products (i.e. 10 mg tablets and 40 mg tablets) to the XEVMPD:

"Full Presentation Name" (AP.13.1) = COMET 10 mg + 40 mg film-coated tablets

"Authorisation Number" (AP.12.4) = EU/1/13/999/001

"EU Number" (AP.12.8) = EU/1/13/999/001

"Package Description" (AP.13.7) = Blister (PVC-Alu) – 14 x 10 mg + 14 x 40 mg tablets

EXAMPLE 6

Marketing authorisation has been granted for a centrally authorised medicinal product 'TRADENAME XYZ 50 U/ml and 100 U/ml Concentrate for solution for infusion'.
The marketing authorisation holder is company MAH-LMN.

The marketing authorisation numbers and the corresponding package descriptions are:

EU/1/03/000/001: TRADENAME XYZ - 100 U/ml - Concentrate for solution for infusion - Intravenous use - vial (glass) - 5 ml (100 U/ml) – 1 vial

EU/1/03/000/002: TRADENAME XYZ - 100 U/ml - Concentrate for solution for infusion - Intravenous use - vial (glass) - 5 ml (100 U/ml) - 10 vials

EU/1/03/000/003: TRADENAME XYZ - 50 U/ml - Concentrate for solution for infusion - Intravenous use - vial (glass) - 5 ml (50 U/ml) - 1 vial

EU/1/03/000/004: TRADENAME XYZ - 50 U/ml - Concentrate for solution for infusion - Intravenous use - vial (glass) - 5 ml (50 U/ml) – 10 vials

Based on the principles outlined above (different authorisation numbers for each presentation) the marketing authorisation holder should submit four medicinal product entries to the XEVMPD:

AMP entity 1:

"Full Presentation Name" (AP.13.1) = TRADENAME XYZ 100 U/ml Concentrate for solution for infusion

"Authorisation Number" (AP.12.4) = EU/1/03/000/001

"EU Number" (AP.12.8) = EU/1/03/000/001

"Package Description" (AP.13.7) = 1 vial

AMP entity 2:

'Full Presentation Name' field = TRADENAME XYZ 100 U/ml Concentrate for solution for

infusion
 "Authorisation Number" (AP.12.4) = EU/1/03/000/002
 "EU Number" (AP.12.8) = EU/1/03/000/002
 "Package Description" (AP.13.7) = 10 vial

AMP entity 3:

"Full Presentation Name" (AP.13.1) = TRADENAME XYZ 50 U/ml Concentrate for solution for infusion
 "Authorisation Number" (AP.12.4) = EU/1/03/000/003
 "EU Number" (AP.12.8) = EU/1/03/000/003
 "Package Description" (AP.13.7) = 1 vial

AMP entity 4:

"Full Presentation Name" (AP.13.1) = TRADENAME XYZ 50 U/ml Concentrate for solution for infusion
 "Authorisation Number" (AP.12.4) = EU/1/03/000/004
 "EU Number" (AP.12.8) = EU/1/03/000/004
 "Package Description" (AP.13.7) = 10 vial

Table 1a- Authorised medicinal product – language requirements

Medicinal Product Authorisation Procedure (AP.12.2)	Country of authorisation (AP.12.1)	Medicinal Product Data Elements (AP.13.1-AP.13.6)	Substance Name* (PP.ACT.1, PP.ADJ.1, PP.EXC.1)	Attachment: Summary of Product Characteristics (SmPC) (AP.PPI.1)
Centralised Procedure (CAP)	EU Member states	English	All official EU languages	English (Other languages available at the Agency)
	Iceland, Liechtenstein and Norway (IS/LI/NO)	English	National language(s) of the country of authorisation	English + National language(s) of the country of authorisation where available
Mutual Recognition Procedure (MRP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation	National language(s) of the country of authorisation	National language(s) of the country of authorisation (Common approved English text acceptable only if national SmPCs are not available)**
Decentralised Procedure (DCP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation	National language(s) of the country of authorisation	National language(s) of the country of authorisation (Common approved English text acceptable only if national SmPCs are not available)**

Medicinal Product Authorisation Procedure (AP.12.2)	Country of authorisation (AP.12.1)	Medicinal Product Data Elements (AP.13.1-AP.13.6)	Substance Name* (PP.ACT.1, PP.ADJ.1, PP.EXC.1)	Attachment: Summary of Product Characteristics (SmPC) (AP.PPI.1)
National Procedure (NAP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation	National language(s) of the country of authorisation	National language(s) of the country of authorisation

* Plant Latin binominal names or Latin herbal preparation names of authorised medicinal products if reflected in the SmPC are also acceptable

** When the SmPC in the national language becomes available it must be provided in the context of the data maintenance; i.e. when the variation leads to changes as listed in section Transition maintenance phase - Electronic submission plan

List of official languages per country can be found on the [Agency's website](#).

1.1.1. Submission of medicinal products authorised in EEA countries outside the EU

In general Iceland, Liechtenstein and Norway, have, through the EEA agreement, adopted the complete Union *acquis* on medicinal products and are consequently applying the EU rules governing marketing authorisation procedures (i.e. national, centralised, decentralised and mutual recognition procedures). However, the Commission's decisions (including decisions granting Marketing Authorisations) do not directly confer rights and obligations to holders of a marketing authorisation in these countries. The marketing authorisations granted by the European Commission have to be transposed by the competent authorities of Iceland, Liechtenstein and Norway through corresponding decisions on the basis of relevant national laws. In such a case these marketing authorisations granted in Iceland, Liechtenstein and Norway are legally separate from the Commission's decision granting MA.

Therefore, separate entries for the marketing authorisations granted in Iceland, Liechtenstein and Norway should be submitted in the XEVMPD under Article 57(2) requirements.

For medicinal products authorised in Liechtenstein, Norway and Iceland in the centralised procedure the applicable country code (i.e. LI/NO/IS) must be specified.

1.1.1.1. Submission of medicinal products authorised in Liechtenstein

It is clarified in the [Notice to Applicants \(Volume 2A, Chapter 1\)](#) that on the basis of a bilateral agreement between **Liechtenstein** and **Austria** automatic recognition of the Marketing Authorisations granted in *Mutual Recognition Procedure (MRP)* or *Decentralised Procedure (DCP)* is operational. This allows Liechtenstein to use Marketing Authorisations granted by Austria if the applicants have identified Liechtenstein as CMS in the application form submitted with MRP or DCP applications. At the end of the procedures, Austria grants authorisations that are recognised by Liechtenstein. This marketing authorisation can be considered as a marketing authorisation granted in accordance with the pharmaceutical *acquis* for the purpose of EU legislation.

Therefore the marketing authorisation of these products has to fulfil requirements provided for in, *inter alia*, Regulation (EU) 726/2004 and Directive 2001/83/EC.

- The attachment to be used for reference in a medicinal product entity is an Austrian SmPC.
- The data elements AP.13.1 - AP.13.6 must however be provided in German.

In the Notice to Applicants (Volume 2A, Chapter 1) it is also clarified that on the basis of a bilateral agreement between **Liechtenstein** and **Switzerland**, a Swiss marketing authorisation is effective in Liechtenstein. This recognition has no effects outside the customs union between Switzerland and Liechtenstein. Consequently, a marketing authorisation granted by the Swiss authorities and recognised by Liechtenstein, while Switzerland does not apply the EU pharmaceutical *acquis*, cannot be considered as a marketing authorisation granted in accordance with the pharmaceutical *acquis* for the purpose of EU legislation and therefore falls outside the scope of, *inter alia*, Regulation (EU) 726/2004 and Directive 2001/83/EC.

Therefore, marketing authorisations granted by the Swiss authorities and recognised by Liechtenstein fall out of scope of Article 57(2) requirements and do not therefore need to be submitted to the XEVMPD per Article 57(2) requirements.

Table 1b - Requirements for AMP records and attachments for countries with more than one national language

Country	National language(s)	AMP record required?	Attachment to be used for reference	Comment	Language to be used to enter data elements in fields AP.13.1 - AP.13.6
Belgium	Dutch	Yes	SmPC		Dutch
	French	Yes	SmPC		French
	German	Yes	PIL	Since there is no SmPC in German, the PIL is to be used The document granting authorisation/renewal should also be provided if the authorisation number is not stated in the referenced PIL	German
Finland	Finnish	Yes	SmPC		Finnish
	Swedish	Yes	PIL	Since there is no SmPC in Swedish, the PIL is to be used The document granting authorisation/renewal should also be provided if the authorisation	Swedish

Country	National language(s)	AMP record required?	Attachment to be used for reference	Comment	Language to be used to enter data elements in fields AP.13.1 - AP.13.6
				number is not stated in the referenced PIL	
Ireland	English	Yes	SmPC		English
	Irish	No	n/a	Authorisations are not issued in Irish and no SmPC/PIL exists in this language	n/a
Luxembourg*	French	Yes	SmPC or an equivalent document (e.g. PIL or similar text as authorised by the Authorising Body)	French or Belgian SmPC/PIL in French can be used The document granting authorisation/renewal should also be provided if the authorisation number is not stated in the referenced SmPC/PIL	French
	German	Yes	SmPC or an equivalent document (e.g. PIL or similar text as authorised by the Authorising Body)	German, Austrian or Belgian SmPC/PIL in German can be used The document granting authorisation/renewal should also be provided if the authorisation number is not stated in the referenced SmPC/PIL	German
	Luxemburgish	No	n/a	Authorisations are not issued in Luxemburgish and no SmPC/PIL exists in this language	n/a
Malta	English	Yes	SmPC	The document granting authorisation/renewal should also be provided if the authorisation number is not stated in the referenced SmPC	English
	Maltese	No		Authorisations are not	n/a

Country	National language(s)	AMP record required?	Attachment to be used for reference	Comment	Language to be used to enter data elements in fields AP.13.1 - AP.13.6
				issued in Maltese and no SmPC/PIL exists in this language	

* Table 1b covers the scenario when the French as well as the German SmPC/PIL are provided to the Luxembourgish Authority. If the MAH decided to provide only the French SmPC/PIL, or only the German SmPC/PIL to the Luxembourgish Authority, then only one product entity referencing the applicable document should be submitted in the XEVMPD.

Where, in exceptional circumstances, the national SmPC for **non-centrally authorised products** (MRPs/DCPs/NAPs) is not available a similar text (i.e. the English common text, package information leaflet or other similar text as authorised by the Authorising Body) can be used as an attachment for the submission in the XEVMPD. The data elements AP.13.1 - AP.13.6 must however be provided in the language of the country where the marketing authorisation applies.

Table 2 - Art 57(2) data element requirements overview for authorised medicinal product submission

Reference Code	Schema Field Name	EVWEB Field Label	Rules for Art 57(2) submission:	Guidance Link
			M - Mandatory M*- Mandatory with conditions O - Optional	
	Authorised Product elements M.AP Authorised product		M	
@ AP..1	(@)operationtype	Operation Type	M	Available operation types to be used in an XEVPRM
AP.1	localnumber		M*	1.2.1.

AP.2	ev_code	EV Code	M*	1.2.2.
AP.3	newownerid	New Owner ID	EMA Use Only	1.2.3.
AP.4	mahcode	MAH	M	1.2.4.
@ AP.4..1	(@)resolutionmode		M	
AP.5	qppvcode	QPPV	M	1.2.5.
AP.6	mflcode	Master File Location	M*	1.2.6.
@ AP.6..1	(@)resolutionmode		M*	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
AP.7	enquiryemail	PhV Enquiry Email	M	1.2.7.
AP.8	enquiryphone	PhV Enquiry Phone	M	1.2.8.
AP.9	senderlocalcode	Sender Local Code	O	1.2.9.
AP.10	infodateformat		O	1.2.10.
AP.11	infodate	Info Date	M*	1.2.11.
AP.14	comments	Comment	M*	1.2.16.
	Authorised Product – Authorisation element AP.12 authorisation		M	
AP.12.1	authorisationcountrycode	Authorisation Country Code	M	1.2.12.1.
AP.12.2	authorisationprocedure	Authorisation Procedure	M	1.2.12.2.
AP.12.3	authorisationstatus	Authorisation Status	M	1.2.12.3.
AP.12.4	authorisationnumber	Authorisation Number	M	1.2.12.4.
AP.12.5	authorisationdate	Authorisation/Renewal Date	M	1.2.12.5. EV Web field label changed from "Authorisation Date" to "Authorisation/Renewal Date"
AP.12.6	authorisationdateformat		M	1.2.12.6.

AP.12.7	mrpnumber	MRP/DCP/EM EA Number	M*	1.2.12.7. EV Web field label changed from "MRP/DCP Number" to "MRP/DCP/EMA Number"
AP.12.8	eunumber	EU Number	M*	1.2.12.8.
AP.12.13	legalbasis	Legal Basis	M	1.2.12.13.
AP.12.9	orphandrug	Orphan Drug	M	1.2.12.9.
AP.12.10	Intensivemonitoring	Additional Monitoring	O	1.2.12.10. EV Web field label changed from "Intensive Monitoring" to "Additional Monitoring"
AP.12.11	withdrawndateformat		M*	1.2.12.11.
AP.12.12	withdrawndate	Invalidated Date	M*	1.2.12.12.
	Elements within the Medicinal Product Types element AP.XX medicinalproducttype		M	New element applicable from June 2014
AP.12.MPTs	medicinalproducttype	Medicinal Product Types	M*	1.2.12.14.
	Elements within the Authorised Product – Presentation Name element AP.13 presentationname		M	
AP.13.1	productname	Full Presentation Name	M	1.2.13.1.
AP.13.2	productshortname	Product Short Name	M*	1.2.13.2.
AP.13.3	productgenericname	Product INN/Commo n Name	M*	1.2.13.3. EV Web Field label changed from "Product Generic Name" to "Product INN/Common Name"

AP.13.4	productcompanyname	Product Company Name	M*	1.2.13.4.
AP.13.5	productstrength	Product Strength Name	M*	1.2.13.5.
AP.13.6	productform	Product Form Name	M*	1.2.13.6.
AP.13.7	packagedesc	Package Description	O	1.2.15.
	Elements within the Authorised Pharmaceutical Forms element AP.XX authpharmforms		M	
AP.APF	authpharmform		M	1.2.14.
	The Pharmaceutical Product – Active Ingredient element PP.ACT activeingredient		M	
PP.ACT.1	substancecode	Substance Name	M	1.2.17.4.
@ PP.ACT.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
PP.ACT.2	concentrationtypecode	Amount Value Type	M	1.2.17.6.
PP.ACT.3	lowamountnumervalue	Low Amount Numerator Value	M	(Low Amount) Numerator Value (PP.ACT.3)
PP.ACT.4	lowamountnumerprefix	Low Amount Numerator prefix	M	(Low Amount) Numerator Prefix (PP.ACT.4)
PP.ACT.5	lowamountnumerunit	Low Amount Numerator Unit	M	(Low Amount) Numerator Unit (PP.ACT.5)
PP.ACT.6	lowamountdenomvalue	Low Amount Denominator Value	M	(Low Amount) Denominator Value (PP.ACT.6)

PP.ACT.7	lowamountdenomprefix	Low Amount Denominator prefix	M	(Low Amount) Denominator Prefix (PP.ACT.7)
PP.ACT.8	lowamountdenomunit	Low Amount Denominator Unit	M	(Low Amount) Denominator Unit (PP.ACT.8)
PP.ACT.9	highamountnumervalue	High Amount Numerator Value	M*	High Amount Numerator Value (PP.ACT.9)
PP.ACT.10	highamountnumerprefix	High Amount Numerator prefix	M*	High Amount Numerator Prefix (PP.ACT.10)
PP.ACT.11	highamountnumerunit	High Amount Numerator Unit	M*	High Amount Numerator Unit (PP.ACT.11)
PP.ACT.12	highamountdenomvalue	High Amount Denominator Value	M*	High Amount Denominator Value (PP.ACT.12)
PP.ACT.13	highamountdenomprefix	High Amount Denominator prefix	M*	High Amount Denominator Prefix (PP.ACT.13)
PP.ACT.14	highamountdenomunit	High Amount Denominator Unit	M*	High Amount Denominator Unit (PP.ACT.14)
	The Pharmaceutical Product – Adjuvant elements PP.ADJ adjuvant		M*	
PP.ADJ.1	substancecode	Substance Name	M	1.2.17.10.
@ PP.ADJ.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
PP.ADJ.2	concentrationtypecode	Amount Value Type	M	Same principle as described in 1.2.17.6.
PP.ADJ.3	lowamountnumervalue	Low Amount Numerator Value	M	Same principle as described in (Low Amount) Numerator Value (PP.ACT.3)

PP.ADJ.4	lowamountnumerprefix	Low Amount Numerator prefix	M	<i>Same principle as described in (Low Amount) Numerator Prefix (PP.ACT.4)</i>
PP.ADJ.5	lowamountnumerunit	Low Amount Numerator Unit	M	<i>Same principle as described in (Low Amount) Numerator Unit (PP.ACT.5)</i>
PP.ADJ.6	lowamountdenomvalue	Low Amount Denominator Value	M	<i>Same principle as described in (Low Amount) Denominator Value (PP.ACT.6)</i>
PP.ADJ.7	lowamountdenomprefix	Low Amount Denominator prefix	M	<i>Same principle as described in (Low Amount) Denominator Prefix (PP.ACT.7)</i>
PP.ADJ.8	lowamountdenomunit	Low Amount Denominator Unit	M	<i>Same principle as described in (Low Amount) Denominator Unit (PP.ACT.8)</i>
PP.ADJ.9	highamountnumervalue	High Amount Numerator Value	M*	<i>Same principle as described in High Amount Numerator Value (PP.ACT.9)</i>
PP.ADJ.10	highamountnumerprefix	High Amount Numerator prefix	M*	<i>Same principle as described in High Amount Numerator Prefix (PP.ACT.10)</i>
PP.ACT.11	highamountnumerunit	High Amount Numerator Unit	M*	<i>Same principle as described in High Amount Numerator Unit (PP.ACT.11)</i>
PP.ADJ.12	highamountdenomvalue	High Amount Denominator Value	M*	<i>Same principle as described in High Amount Denominator Value (PP.ACT.12)</i>
PP.ADJ.13	highamountdenomprefix	High Amount Denominator prefix	M*	<i>Same principle as described in High Amount Denominator Prefix (PP.ACT.13)</i>
PP.ADJ.14	highamountdenomunit	High Amount Denominator Unit	M*	<i>Same principle as described in High Amount Denominator Unit (PP.ACT.14)</i>
	The Pharmaceutical Product – Excipient element PP.EXC excipient		M*	

PP.EXC.1	substancecode	Substance Name	M	1.2.17.8.
@ PP.EXC.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
PP.EXC.2	concentrationtypecode	Amount Value Type	O	<i>Same principle as described in 1.2.17.6.</i>
PP.EXC.3	lowamountnumervalue	Low Amount Numerator Value	O	<i>Same principle as described in (Low Amount) Numerator Value (PP.ACT.3)</i>
PP.EXC.4	lowamountnumerprefix	Low Amount Numerator prefix	O	<i>Same principle as described in (Low Amount) Numerator Prefix (PP.ACT.4)</i>
PP.EXC.5	lowamountnumerunit	Low Amount Numerator Unit	O	<i>Same principle as described in (Low Amount) Numerator Unit (PP.ACT.5)</i>
PP.EXC.6	lowamountdenomvalue	Low Amount Denominator Value	O	<i>Same principle as described in (Low Amount) Denominator Value (PP.ACT.6)</i>
PP.EXC.7	lowamountdenomprefix	Low Amount Denominator prefix	O	<i>Same principle as described in (Low Amount) Denominator Prefix (PP.ACT.7)</i>
PP.EXC.8	lowamountdenomunit	Low Amount Denominator Unit	O	<i>Same principle as described in (Low Amount) Denominator Unit (PP.ACT.8)</i>
PP.EXC.9	highamountnumervalue	High Amount Numerator Value	O	<i>Same principle as described in High Amount Numerator Value (PP.ACT.9)</i>
PP.EXC.10	highamountnumerprefix	High Amount Numerator prefix	O	<i>Same principle as described in High Amount Numerator Prefix (PP.ACT.10)</i>
PP.EXC.11	highamountnumerunit	High Amount Numerator Unit	O	<i>Same principle as described in High Amount Numerator Unit (PP.ACT.11)</i>

PP.EXC.12	highamountdenomvalue	High Amount Denominator Value	O	<i>Same principle as described in High Amount Denominator Value (PP.ACT.12)</i>
PP.EXC.13	highamountdenomprefix	High Amount Denominator prefix	O	<i>Same principle as described in High Amount Denominator Prefix (PP.ACT.13)</i>
PP.EXC.14	highamountdenomunit	High Amount Denominator Unit	O	<i>Same principle as described in High Amount Denominator Unit (PP.ACT.14)</i>
	The Pharmaceutical Product element PP pharmaceuticalproduct		M	
PP.1	pharmformcode	Administrable Pharmaceutical Form	M	1.2.17.1. EV Web Field label changed from "Pharmaceutical Form" to "Administrable Pharmaceutical Form"
@PP.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
	Elements within the Authorised Product – Product Indication element AP.IND productindication		M	
AP.IND.1	meddraversion	MedDRA Version	M	1.2.19.1.
AP.IND.2	meddralevel	MedDRA Level	M	1.2.19.2.
AP.IND.3	meddracode	MedDRA Term	M	1.2.19.3.

	The Pharmaceutical Product – Administration Route element PP.AR adminroute		M	
PP.AR.1	adminroutecode	Route Of Administration	M	1.2.17.2.
@ PP.AR.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
	Elements within the Authorised Product – ATC element AP.ATC productatc		M	
AP.ATC.1	atccode	ATC Code	M	1.2.18.
@ AP.ATC.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
	The Pharmaceutical Product – Medical Device elements		M*	
PP.MD.1	medicaldevicecode	Medical Device	M	1.2.17.12.
	The Authorised Product – Printed Product Information Attachment element AP.PPI ppiattachment		M	
AP.PPI.1	attachmentcode	Product Attachment	M	1.2.21.1.

@ AP.PPI.1..1	(@)resolutionmode		M	See Chapter 3.I of the Detailed guidance: Extended EudraVigilance product report message (XEVPRM) technical specifications
AP.PPI.2	validitydeclaration	Validity Declaration	M*	1.2.21.2.

1.2. Authorised medicinal product - element structure

The below schema shows the individual data fields/sections to be provided for an authorised medicinal product submission.

The XEVPRM field description may differ from EVWEB field description and so each field name also references the assigned XEVPRM field code (e.g. AP.13.4, AP.PPI.1). For example:

Field AP.13.1

XEVPRM field description = "productname"

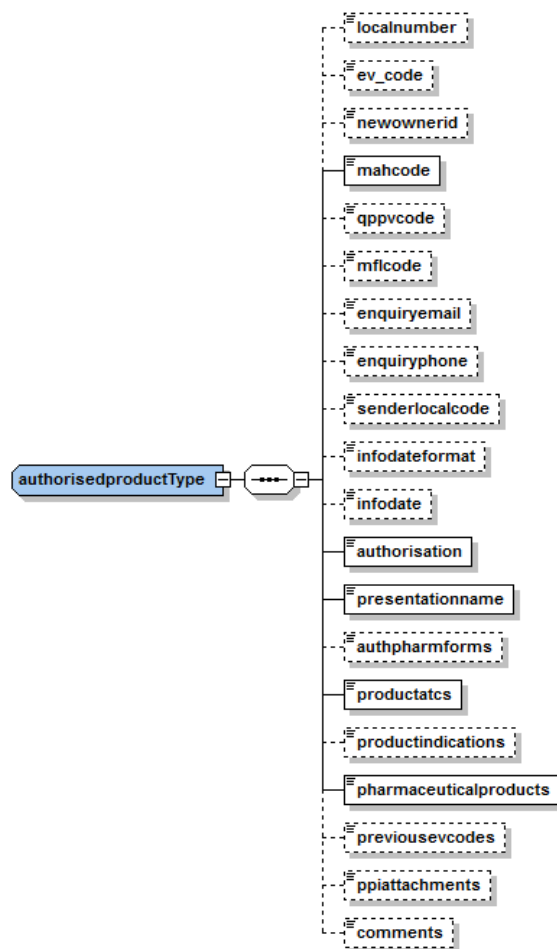
EVWEB field description = "Full Presentation Name"

Field AP.13.3

XEVPRM field description = "productgenericname"

EVWEB field description = "Product INN/Common Name"

In 16 June 2014, the XEVPRM schema was amended to allow for submission of additional information:



1.2.1. Local Number (AP.1)

A unique reference number for an AMP entity in an XEVPRM after an operation type 'Insert' (1) was applied must be assigned.

When an authorised medicinal product is submitted in an XEVPRM with the operation 'Insert' (1) a local number must be assigned to this product. When the XEVPRM Acknowledgement is received, and providing that the submission was successful, this local number should be used to identify the corresponding EV Code.

EXAMPLE: XEVPRM - Insert of an AMP

```
<authorisedproducts>
<authorisedproduct operationtype="1">
  <localnumber>9</localnumber>
  <presentationname>
  <productname>Example ProductXYZ</productname>
```

EXAMPLE - XEVPRM Acknowledgement received following an insert of an AMP

```
- <reportacknowledgment>
  <reportname>AUTHORISEDPRODUCT</reportname>
  <localnumber>9</localnumber>
  <ev_code>PRD123456</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully Version 1 The product will be
    validated by the EMA in due course. When validated you will receive a further
    acknowledgement with the message number: "Product Validated PRD123456
    Version [Version Number] / [Date and Time]"</operationresultdesc>
</reportacknowledgment>
</acknowledgment>
</evprmack>
```

See also document [Quality Control of medicinal product data submitted as per the legal requirement introduced by Article 57\(2\) of Regulation \(EC\) No 726/2004](#) for related information.

1.2.2. EV Code (AP.2)

The EudraVigilance (EV) Code of the authorised medicinal product must be specified if the operation type is NOT an 'Insert' (1).

I.e. if a maintenance related operations are performed on an authorised medicinal product entity which was successfully inserted in the XEVMPD, the EV Code of the AMP entity must be referenced in this data field.

1.2.3. New Owner ID (AP.3)

This field is reserved for EMA use only.

1.2.4. Marketing authorisation holder (MAH) code (AP.4)

Marketing authorisation holder code corresponding to the legal entity of the medicinal product in a given country as indicated in section 7. Marketing Authorisation Holder of the SmPC must be specified.

- If the MAH organisation was previously successfully submitted in the XEVMPD and an MAH organisation EV Code had been assigned, the MAH can be selected from the available EudraVigilance look-up table (EVWEB users). Gateway users should populate the 'MAH code' field (AP.4) with the assigned organisation EV Code received in the XEVPRM Acknowledgement.

List of available MAH organisations with their assigned EV Codes can be found in the XEVMPD look-up table and in the controlled vocabulary (CV) lists published on the [Agency's website](#) - see "eXtended Eudravigilance Product Dictionary (XEVMPD) organisations".

See also section [1.6. Initial submission of a marketing authorisation holder \(MAH\) organisation](#) of this document for related information.

NOTE 1

The MAH XEVMPD look-up table and the published Organisation CV list are different from the list of organisations registered with EV (i.e. in the EudraVigilance registration database). The list of organisations registered with Eudravigilance is the list of all registered stakeholders (regulators, pharmaceutical industry and sponsors) and is accessible to registered users in the restricted area of the EudraVigilance Human website.

The "*Extended EudraVigilance product report message (XEVMPD) Organisations*" list available as part of the controlled vocabularies published on the Agency's website and retrievable in XEVMPD Data Entry Tool (EVWEB) contains details of the marketing authorisation holder organisations available in the XEVMPD. These organisation entities should be referenced as applicable in the medicinal product information submitted.

- If the MAH organisation entity does not exist in the XEVMPD, the MAH information can be added using the 'Organisation' section of the XEVPRM. See section [1.6. Initial submission of a marketing authorisation holder \(MAH\) organisation](#) of this document for further information on how to submit an MAH organisation in the XEVMPD.

1.2.5. Qualified Person responsible for Pharmacovigilance (QPPV) code (AP.5)

The QPPV code of the QPPV responsible for the authorised medicinal product must be specified.

- The EU QPPV, and where such does not exist, the local QPPV/Responsible person (e.g. for purely national authorisations) should [register with EudraVigilance](#). From 26 July 2018 EU QPPV/responsible person/local QPPV must self-register in the [EMA Account Management Platform](#). Please refer to the information available on the [EudraVigilance: how to register webpage](#), section Registering individual users (new).
- Following the registration, a QPPV Code is assigned. The QPPV code assigned by the Agency's EudraVigilance (EV) database and can be retrieved from:
 - the EudraVigilance website (restricted area accessible for registered users only) under 'QPPV list' (by Gateway/EVWEB users):



- or in the EudraVigilance look-up table in EVWEB (by EVWEB users):

Description	Name/Value	
Type	Authorised	
Is EMA Owned		
Operation Type	Insert	
New Owner ID		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		
PhV enquiry Phone		
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		
MRP/DCP/EMEA Number		
QPPVs		

- if the requested QPPV does not exist in the XEVMPD, please refer to section [1.3. Initial submission of a QPPV information](#) of this document for information on how to submit QPPV information in the XEVMPD.

MAHs must ensure that the QPPV Code referenced in their AMPs is a valid QPPV Code referring to a current QPPV (e.g. the QPPV Code is not "retired" in the EV Registration database).

1.2.6. Pharmacovigilance System Master File Location (PSMFL) code (AP.6)

The Pharmacovigilance System Master File Location (PSMFL) code of the place where the PSMF for the authorised medicinal product is located must be specified if the PSMFL information was submitted in the XEVMPD and the PSMFL Code is available.

MFL EV Code is a unique code assigned by the XEVMPD to a specific PSMF and PSMF location.

- If the Master File Location information was previously successfully submitted in the XEVMPD and a PSMFL EV Code had been assigned, the PSMFL can be selected from the available EudraVigilance look-up table (EVWEB users). Gateway users should populate the 'MFL' field (AP.6) with the assigned MFL EV Code received in the XEVPRM Acknowledgement.
- If the required Master File Location does not exist in the XEVMPD, the Master File Location information can be added using the 'Master File Location' section of the XEVPRM and submitted in the XEVMPD.

Further information on what triggers the request of PSMFL EV Code and how to submit MFL information in the XEVMPD are available in section [1.11. Initial submission of a Pharmacovigilance System Master File \(PSMF\) information](#) of this document.

Information on how the PSMFL entity should be maintained is described in section [2.3. Maintenance of a Pharmacovigilance System Master File Location \(PSMFL\) entity.](#)

1.2.7. Pharmacovigilance enquiry email (AP.7)

The email address where enquiries related to Pharmacovigilance can be submitted must be specified.

The marketing authorisation holder needs to decide, which email address they wish to specify for dealing with Pharmacovigilance enquiries. The contact information for Pharmacovigilance enquires (e-mail and phone) will be made [public](#) by the Agency.

1.2.8. Pharmacovigilance enquiry phone (AP.8)

The phone number where enquiries related to Pharmacovigilance can be directed must be specified.

The marketing authorisation holder needs to decide, which phone number they wish to specify for dealing with Pharmacovigilance enquiries. It may be the same as the phone number of the QPPV. The contact information for Pharmacovigilance enquires (e-mail and phone) will be made [public](#) by the Agency.

1.2.9. Sender local code (AP.9)

The sender local code for the authorised medicinal product used by the marketing authorisation holder for internal reference purposes may be specified.

The sender local code specified by the MAH is not used in the XEVMPD for maintenance. It can be any technical code.

1.2.10. Info date format (AP.10)

Format of the info date should correspond to "102" for "CCYYMMDD".

1.2.11. Info date (AP.11)

The date when the lifting of suspension of the marketing authorisation becomes effective must be specified when "Authorisation Status" changes from "Valid - Suspended" to any "Valid" status.

It is not technically possible to specify a future date in this data element (i.e. the date must either be the same as the date of submission or precede the date of submission of your XEVPRM).

"Info date" field (AP.11) is linked to the "Authorisation status" information.

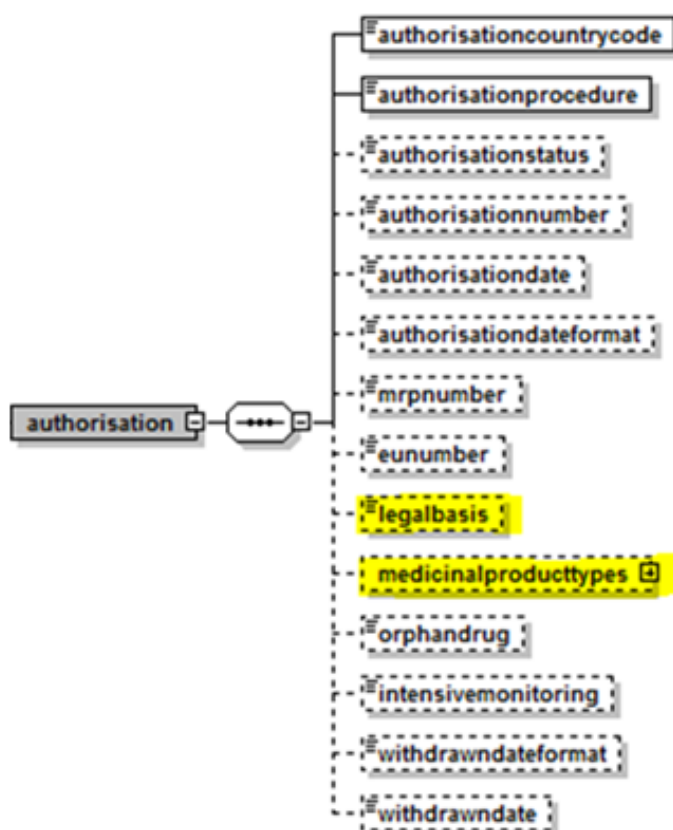
When the "Authorisation status" (AP.12.3) changes from "Valid – Suspended (2)" to:

- Valid (1); or
- Valid – Renewed/Varied Marketing Authorisation (8); or
- Valid - Transferred Marketing Authorisation (9);

the data element in "Info date" field (AP.11) should indicate the date when the lifting of the suspension of the marketing authorisation becomes effective.

1.2.12. AMP - Authorisation details element structure (AP.12)

XEVPRM schema of Authorisation section
in use as of **16 June 2014**



1.2.12.1. Authorisation country code (AP.12.1)

The country code of the country of authorisation must be specified.

The country code is to be specified using the ISO-3166-1 standard. The official list of ISO 3166-1 country codes is maintained by the [International Organization for Standardization \(ISO\)](http://www.iso.org).

- For medicinal products authorised through the centrally authorised procedure, "European Union (EU)" should be specified.
 - For medicinal products authorised in Liechtenstein, Norway and Iceland through the centralised procedure the applicable country code (i.e. LI/NO/IS) must be specified.
- For medicinal products authorised through the national or MRP/DCP procedure, the applicable EEA country should be specified.
- For medicinal products authorised in a non-EU authorisation procedure a non-EEA country should be specified. Medicinal products authorised through a non-EU procedure are submitted in the XEVMPD on voluntary basis. Such products are not within the scope of Article 57(2) requirements.

See also *Table 1a- Authorised medicinal product – language* requirements for related information.

NOTE 2

- For United Kingdom, the code "GB" should be used as the officially assigned code in accordance with the [ISO country codes](#) in case of voluntary submission of information on medicinal products with marketing authorisation valid in England, Wales and Scotland.

"UK" is a "reserved code" assigned at the request of the national ISO member bodies, governments and international organizations. This applies to certain code elements required to support a particular application as specified by the requesting body and limited to such use. Any further use of such code elements is subject to approval by the ISO 3166/MA. More information about the reserved codes can be found on the [ISO website](#).

- For Greece, the code "GR" (not "EL") should be used as the officially assigned code in accordance with the [ISO country codes](#).
- For "United Kingdom (Northern Ireland)" the assigned country code "XI" should be used in submissions of information on medicinal products with marketing authorisation valid in the territory of Northern Ireland.

1.2.12.2. Authorisation procedure (AP.12.2)

The procedure through which the medicinal product was authorised must be specified.

List of available authorisation procedure values can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the [Agency's website](#) - see "[eXtended Eudravigilance Product Dictionary \(XEVMPD\) authorisation procedures](#)".

- EU authorisation procedures - Centralised Procedure (1):** must be selected when entering centrally authorised medicinal product.

The authorisation country code (AP.12.1) must be specified as "EU".

For medicinal products authorised in Liechtenstein, Norway and Iceland through the **centralised procedure** the applicable country code (i.e. LI/NO/IS) must be specified.

See the Commission's website for information on the [centralised procedure](#).

- EU authorisation procedures - Mutual Recognition Procedure (3):** must be selected when entering mutually recognised medicinal product and in case of a repeat-use procedure.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

See the Commission's website for information on the [mutual recognition procedure](#).

- EU authorisation procedures - National Procedure (4):** must to be selected when entering nationally authorised medicinal products.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

- Non EU authorisation procedure (5):** must be selected when entering medicinal products authorised outside the EEA.

The authorisation country code (AP.12.1) must not be specified as "EU" or any of the EEA countries.

- **EU authorisation procedures - Decentralised Procedure (7):** must be selected when entering medicinal product authorised in decentralised procedure.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

See the Commission's website for information on the [decentralised procedure](#).

- **EU authorisation procedures - Traditional use registration for herbal medicinal products (11):** must be selected when entering herbal medicinal products registered under the Traditional Herbal Medicines Registration Scheme.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

- **EU authorisation procedures - Simplified registration procedure for homeopathic medicinal products (12):** must be selected when entering homeopathic medicinal products registered through the simplified registration procedure.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

- **EU other approval/authorisation procedure (13)** must be selected in case of voluntary submission of medicinal product information not authorised in the European Union (EU) and the European Economic Area (EEA), and administered under emergency use, compassionate use or other national schemes.

The authorisation country code (AP.12.1) must be specified as one of the EEA countries.

NOTE 3

- In case of voluntary submission of medicinal product falling outside the scope of Article 57(2) requirements and for which a marketing authorisation is not granted (e.g. herbal medicinal product with no registration) the value "EU authorisation procedures - National Procedure (4)" should be selected.
 - Indication of the legal basis or the medicinal product type must be provided in data fields "Legal Basis" (AP.12.13) and "Medicinal Product Type" (AP.12.MPTs).
 - The "Authorisation country code" (AP.12.1) must be specified as one of the EEA countries.
- In case of voluntary submission of information on medicinal products without a marketing authorisation granted in the EU/EEA, which are provided under emergency use, compassionate use or other national schemes, and which fall outside the scope of Article 57(2) requirements, the value "**EU other approval/authorisation procedure (13)**" should be selected.
 - Indication of the legal basis or the medicinal product type must be provided in data fields "Legal Basis" (AP.12.13).
 - The "Authorisation country code" (AP.12.1) must be specified as one of the EEA countries.

1.2.12.3. Authorisation status (AP.12.3)

The status of the authorisation of a medicinal product must be specified.

The information stated in this field does not refer to the marketing status (i.e. marketed/not marketed).

List of available authorisation status values can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the [Agency's website](#) - see "[eXtended Eudravigilance Product Dictionary \(XEVMPD\) authorisation status](#)".

- **Valid (1):** applicable to a medicinal product for which the marketing authorisation is valid.
- **Valid - Suspended (2):** applicable to a medicinal product for which the marketing authorisation is suspended. When the suspension has been lifted, the status of the medicinal product should be changed either to a "valid" status or to a "not valid" status (e.g. revoked or withdrawn) as applicable.
- **Not valid - Withdrawn by marketing authorisation holder (3):** applicable to a medicinal product for which the marketing authorisation has been withdrawn by the marketing authorisation holder.
- **Not valid - Revoked by Competent Authority (4):** applicable to a medicinal product for which the marketing authorisation has been revoked by a Competent Authority/European Commission.
- **Not valid - Not renewed by Competent Authority (5):** applicable to a medicinal product for which the marketing authorisation has not been renewed by the Competent Authority/European Commission.
- **Not valid - Not submitted for renewal by marketing authorisation Holder (6):** applicable to a medicinal product for which the marketing authorisation holder did not submit a request for renewal.
- **Not valid - Expired due to Sunset Clause (7):** applicable to a medicinal product for which the marketing authorisation has expired due to the [Sunset Clause](#).
- **Valid – Renewed/Varied Marketing Authorisation (8):** applicable to a medicinal product for which the marketing authorisation has been renewed or varied and a new marketing authorisation number has been assigned by the National Competent Authority.
- **Valid - Transferred Marketing Authorisation (9):** applicable to a medicinal product for which the marketing authorisation was transferred from one marketing authorisation holder to another.

This authorisation status is to be used by the new MAH as part of the transfer of marketing authorisation process.

- **Not Valid – Superseded by Marketing Authorisation Renewal/Variation (10):** applicable to a medicinal product for which the marketing authorisation has been renewed or varied and a new marketing authorisation number has been assigned by the National Competent Authority.
- **Not Valid - Superseded by Marketing Authorisation Transfer (11):** applicable to a medicinal product for which the marketing authorisation was transferred from one marketing authorisation holder to another.

This authorisation status is to be used by the former MAH as part of the transfer of marketing authorisation process.

NOTE 4

AMPs for which the marketing authorisation was transferred to another MAH should be submitted in the XEVMPD with the authorisation status "Valid – Transferred Marketing Authorisation" (9). It can change from "Valid – Transferred Marketing Authorisation" to "Valid – Suspended" and then back to "Valid – Transferred Marketing Authorisation".

"Valid – Transferred Marketing Authorisation" can also change to "Valid – Renewed/Varied Marketing Authorisation" but not back to "Valid – Transferred Marketing Authorisation".

Please note that when a marketing authorisation was transferred the authorisation status can never be "Valid" when the new MAH received the previous EV Code (from the previous MAH).

1.2.12.4. Authorisation number (AP.12.4)

Marketing authorisation number assigned by the Competent Authority and as stated in the SmPC must be specified – See [EXAMPLE 7](#).

Only one number must be stated in this data element. If multiple authorisation numbers are stated in the SmPC (e.g. in section 8. Marketing authorisation number(s) of the corresponding SmPC), multiple product entities should be submitted in the XEVMPD. Package size corresponding to the individual authorisation number may be included in the "Package Description" field (AP.13.7) – See [EXAMPLE 8](#).

If the authorisation numbers are specified in the format XXXX/XXX-XXX (e.g. 1234/001-003) then multiple authorised medicinal product entities should be submitted, each referencing the specific authorisation number (i.e. 1234/001, 1234/002, 1234/003).

Scenario 1:

The SmPC of a medicinal product authorised in Romania states the following information:

1. Name of the medicinal product

Paracetamol Plus PharmaK 500 mg comprimate

8. Authorisation number(s)

1234/2014/01-04

Based on the above example, four medicinal product entities should be submitted in the XEVMPD, each referencing the applicable authorisation number (i.e. 1234/2014/01, 1234/2014/02, 1234/2014/03, 1234/2014/04).

Scenario 2:

The SmPC of a centrally authorised medicinal product states the following information:

1. Name of the medicinal product

Macys 100 mg tablets

8. Authorisation number(s)

EU/1/13/016/003-007

Based on the above example, five medicinal product entities should be submitted in the XEVMPD, each referencing the applicable authorisation number (i.e. EU/1/13/016/003, EU/1/13/016/004, EU/1/13/016/005, EU/1/13/016/006, EU/1/13/016/007).

For **centrally authorised medicinal products** the format of the authorisation number must be "EU/1/YY/NNN/NNN" or "EU/1/YY/NNNN/NNN" (as applicable) – see [EXAMPLE 5](#) and [EXAMPLE 9](#).

- For centrally authorised medicinal products (CAPs) the marketing authorisation number as assigned by the European Commission and as stated in section 8. Marketing authorisation number(s) of the SmPC must be entered in the "Authorisation Number" field (AP.12.4) as well as in the "EU Number" field (AP.12.8) – See [EXAMPLE 5](#) and [EXAMPLE 9](#).

EXAMPLE 7

The SmPC of a medicinal product with a valid MA in Northern Ireland states the following information:

1. Name of the medicinal product

Kassa tablets

8. Authorisation number(s)

PL 1234/0001

Based on the information stated in section 8. Authorisation number(s) of the SmPC (i.e. one authorisation number listed), one medicinal product entries should be submitted to the XEVMPD:

"Full Presentation Name" (AP.13.1) = Kassa tablets

"Authorisation Number" (AP.12.4) = PL 1234/0001

EXAMPLE 8

The SmPC of a medicinal product with a valid MA in Northern Ireland states the following information:

1. Name of the medicinal product

Triamcinolone acetonide tablets

8. Authorisation number(s)

PL 12345/0001

PL 12345/0002

Based on the information stated in section 8. Authorisation number(s) of the SmPC (i.e. two authorisation numbers listed), two medicinal product entries should be submitted to the XEVMPD:

AMP entity 1:

"Full Presentation Name" (AP.13.1) = Triamcinolone acetonide tablets

"Authorisation Number" (AP.12.4) = PL 12345/0001

AMP entity 2:

"Full Presentation Name" (AP.13.1) = Triamcinolone acetonide tablets

"Authorisation Number" (AP.12.4) = PL 12345/0002

EXAMPLE 9

AMP authorised in the centralised procedure with EU number: EU/1/23/4569/789 and EMEA number: EMEA/H/C/123456 should be entered in the corresponding fields as follows:

Authorisation Procedure" (AP.12.2) = EU authorisation procedures - Centralised Procedure

"Authorisation Number" (AP.12.4) = EU/1/23/4569/789

"MRP/DCP/EMA Number" (AP.12.7) = EMEA/H/C/123456

"EU Number" (AP.12.8) = EU/1/23/4569/789

1.2.12.5. Authorisation/renewal date (AP.12.5)

The date when the first authorisation was granted by the authorising body or the date when the renewal was granted (whichever is the latest) must be specified in line with section 9. Date of first authorisation/renewal of the authorisation of the SmPC.

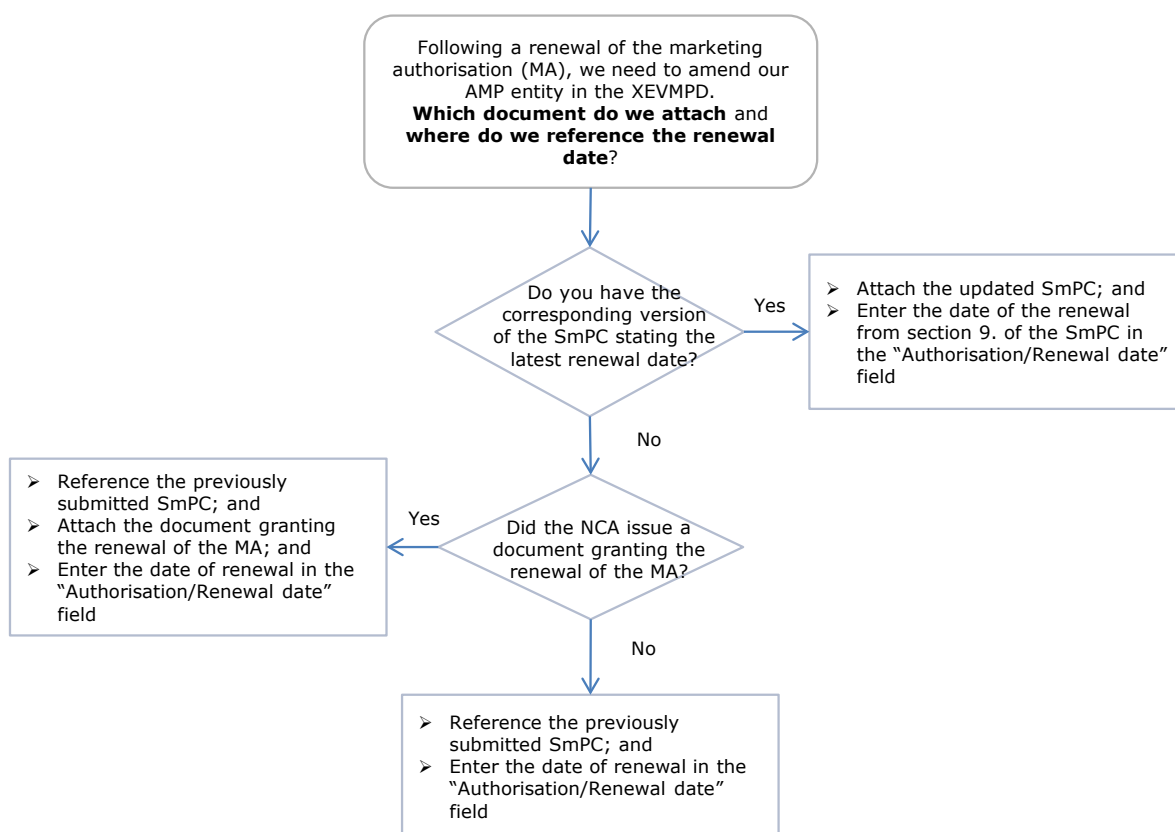
The authorisation date is linked to the regulatory status of the medicinal product:

- The date when **the first authorisation** was granted by the Authorising Body must be specified when there was no prior renewal of the MA and the "Authorisation Status" (AP.12.3) is entered as:
 - "Valid (1); or
 - "Valid - Transferred Marketing Authorisation (9)".
- The date when **the renewal** was granted by the Authorising Body must be specified as applicable when the "Authorisation Status" (AP.12.3) is entered as:
 - "Valid (1); or
 - "Valid – Renewed/Varied Marketing Authorisation (8)"

The authorisation/renewal date is to be specified consisting of year, month and day or year and month.

It is not technically possible to specify a future date in this data element (i.e. the date must either be the same as the date of submission or precede the date of submission of your XEVPRM).

If section 9. of the SmPC does not state the date of renewal, the following guidance should be followed:



1.2.12.6. Authorisation/renewal date format (AP.12.6)

Format of the authorisation/renewal date should correspond to "102" for "CCYYMMDD" or to "610" corresponding to "CCYYMM".

1.2.12.7. MRP/DCP/EMEA number (AP.12.7)

MRP/DCP/EMEA Procedure Number must be specified depending on the applicable authorisation procedure.

Whilst the format of the number for a specific procedure is a unique combination of six sections, i.e. CC/D/nnnn/sss/X/vvv where the "X" represents the type of marketing application to the medicinal product, the number stated in the XEVPRM field "MRP/DCP/EMEA number" (AP.12.7) should not contain the reference to the marketing application (i.e. "MR", "DC" etc.) since the type of marketing authorisation is in the XEVMPD captured in the "Authorisation procedure" field (AP.12.2).

The format of the MRP/DCP number should be the same as in the SmPC (if included) without "MR", "DC" etc. or as stated in the MR Index on the HMA website, which is a combination of only four sections (CC/D/nnnn/sss).

The procedure tracking number is always a four digit number and the strength number is a three digit number.

Mutual recognition procedure number must be specified when the "Authorisation Procedure" (AP.12.2)" is entered as "EU authorisation procedures - Mutual Recognition Procedure (3)" – See *EXAMPLE 10*.

- MR number for a specific AMP can be found in the MR Index on the [Heads of Medicines Agency's website](#) and/or can be included in the SmPC.
- The format of the MRP number should be the same as in the SmPC (if included, without the reference to the marketing application, i.e. the text "/MR" or "E") or as stated in the MR Index on the [Heads of Medicines Agency's website](#), i.e. without the reference to the marketing application (i.e. the text "/MR" or "E").

Repeat use procedure number should be entered in the "MRP/DCP/EMA number" field (AP.12.7) as stated in the MR Index on the HMA website, i.e. as a combination of only four sections (CC/D/nnnn/sss).

- In case of RUP or line extensions this information is not to be reflected in the procedure number (no addition behind the procedure number UK/H/0234/001/xx => no /xx).

EXAMPLE 10

AMP authorised in mutual recognition procedure with MR number: SE/H/1111/222 and national authorisation number: PL 12345/123 should be entered in the corresponding fields as follows:

"Authorisation Procedure" (AP.12.2) = EU authorisation procedures - Mutual Recognition Procedure
"Authorisation Number" (AP.12.4) = PL 12345/123
"MRP/DCP/EMA Number" (AP.12.7) = SE/H/1111/222
"EU Number" (AP.12.8) = <this field should be left blank>

Decentralised authorisation procedure number must be specified when the "Authorisation Procedure" (AP.12.2)" is entered as "EU authorisation procedures - Decentralised Procedure (7)" – See *EXAMPLE 11*.

- DCP number for a specific AMP can be found in the MR Index on the [Heads of Medicines Agency's website](#) and/or can be included in the SmPC.
- The format of the DCP number should be the same as in the SmPC (if included, without the reference to the marketing application, i.e. the text "/DC") or as stated in the MR Index on the [Heads of Medicines Agency's website](#), i.e. without the reference to the marketing application (i.e. the text "/DC").

EXAMPLE 11

An AMP authorised in the Czech Republic in decentralised procedure with DCP number: DE/H/1111/001/DC and with the authorisation number 11/222/03-C should be entered in the corresponding fields as follows:

"Authorisation Procedure" (AP.12.2) = EU authorisation procedures - Decentralised Procedure
"Authorisation Number" (AP.12.4) = 11/222/03-C
"MRP/DCP/EMA Number" (AP.12.7) = DE/H/1111/001

"EU Number" (AP.12.8) = <this field should be left blank>

EMA procedure number (i.e. "Agency Product Number" as referred to/published on the [Agency's webpage](#)) must be specified when the "Authorisation Procedure" (AP.12.2) is entered as "EU authorisation procedures - Centralised Procedure (1)" – See [EXAMPLE 9](#).

- The format of the EMA procedure number should be EMA six digit procedure number (i.e. EMA/H/C/123456) of a specific CAP can be found on the [EMA website](#).

1.2.12.8. EU number (AP.12.8)

The marketing authorisation number as assigned by the EU Commission and as stated in section 8. Marketing authorisation number(s) of the SmPC must be specified.

When the "Authorisation Procedure" (AP.12.2) is entered as "EU authorisation procedures - Centralised Procedure (1)", the "EU Number" field (AP.12.8), as well as the "Authorisation Number" field (AP.12.4) must be populated with the EU number.

The format of the EU number must be "EU/1/YY/NNN/NNN" or "EU/1/YY/NNNN/NNN" (as applicable) - See [EXAMPLE 5](#) and [EXAMPLE 9](#).

1.2.12.9. Orphan drug status (AP.12.9)

The value indicating whether the AMP is considered an orphan drug medicine must be specified.

The disease (orphan) designation of a medicinal product from the European Medicines Agency's Committee on Orphan Medicinal Products (COMP) must be specified unless the operation type is 'Nullification (4)' or 'Invalidate MA (6)'. One of the following values is to be specified as applicable:

- 1 = Yes
- 2 = No

1.2.12.10. Additional monitoring (AP.12.10)

The value indicating whether the AMP is subject to additional monitoring must be specified.

Indication for additional monitoring (black triangle/symbol) for a specific AMP can be found in the SmPC of the authorised medicinal product.

Indication whether the medicinal product is subject to additional monitoring must be specified referencing one of the available values:

- 1 = medicinal product is subject to additional monitoring
- 2 = medicinal product is NOT subject to additional monitoring

1.2.12.11. Invalidated date format (AP.12.11)

Format of the Invalidated date should correspond to "102" for "CCYYMMDD".

1.2.12.12. Invalidated date (AP.12.12)

The date as of when the "Authorisation status" (AP.12.3) "Not valid" or "Valid - Suspended" becomes effective must be specified depending on the applicable authorisation status.

- **The date of expiry** of the marketing authorisation must be entered in the "Invalidated date" field (AP.12.12) when one of the below values is used in the "Authorisation status" field (AP.12.3) :
 - Not valid - Withdrawn by marketing authorisation holder (3)
 - Not valid - Revoked by Competent Authority (4)
 - Not valid - Not renewed by Competent Authority (5)
 - Not valid - Not submitted for renewal by marketing authorisation Holder (6)
 - Not valid - Expired due to Sunset Clause (7)
- **The date of suspension** of the marketing authorisation must be entered in the "Invalidated date" field (AP.12.12) when the value "Valid – Suspended (2)" is specified in the "Authorisation status" field (AP.12.3).
- **The date of transfer** of the marketing authorisation must be entered in the "Invalidated date" field (AP.12.12) when the value "Not Valid – Superseded by Marketing Authorisation Transfer (11)" is specified in the "Authorisation status" field (AP.12.3).
- **The date of renewal** of the marketing authorisation must be entered in the "Invalidated date" field (AP.12.12) when the value "Not Valid – Superseded by Marketing Authorisation Renewal/Variation (10)" is specified in the "Authorisation status" field (AP.12.3).
- **No value** should be entered in the "Invalidated date" field (AP.12.12) when the marketing authorisation remains valid after the suspension of a marketing authorisation has been lifted - the authorisation status should be changed to one of the other "valid" values (1, 8 or 9) and the date when the suspension was lifted must be specified in the "Info Date" field (AP.11).

For centrally authorised medicinal products, see the below documents for further instructions:

[Renewals: questions and answers](#) and [Sunset-clause monitoring: questions and answers](#).

It is not technically possible to specify a future date in this data element (i.e. the date must either be the same as the date of submission or precede the date of submission of your XEVPRM).

1.2.12.13. Legal basis (AP.12.13)

The description of the legal basis for the marketing authorisation must be specified based on the available values.

One of the available values must be selected:

- Full application (Article 8(3) of Directive No 2001/83/EC) (1)
- Generic application (Article 10(1) of Directive No 2001/83/EC) (2)
- Hybrid application (Article 10(3) of Directive No 2001/83/EC) (3)
- Similar biological application (Article 10(4) of Directive No 2001/83/EC) (4)
- Well-established use application (Article 10a of Directive No 2001/83/EC) (5)
- Fixed combination application (Article 10b of Directive No 2001/83/EC) (6)
- Informed consent application (Article 10c of Directive No 2001/83/EC) (7)
- Traditional use registration application for a herbal medicinal product (Article 16a of Directive No 2001/83/EC) (8)
- Simplified registration application for a homeopathic medicinal product (Article 14 of Directive No 2001/83/EC) (9)
- Medicinal product authorised according to Article 126a of Directive No 2001/83/EC (10)
- Application according to Article 58 of Regulation (EC) No 726/2004 (11)
- Authorisation according to Article 5(1) of Directive 2001/83/EC (12);
- Authorisation according to Article 5(2) of Directive 2001/83/EC (13);
- Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC (14);
- Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC (15);
- Available under Article 83(2) of Regulation (EC) No 726/2004 (16).

NOTE 5

As regard medicinal products for which the legal basis of the marketing authorisation predates Directive 2001/83/EC: taking into account that the pharmaceutical *Acquis communautaire* has been amended over time, the legal basis applicable under the current Union legal framework which corresponds to the legal basis in the legislation that was **applicable at time of submission of your application** must be specified.

NOTE 6

- Where the "Authorisation procedure" (AP.12.2) is specified as "*EU authorisation procedures - Traditional use registration for herbal medicinal products*" (11) the Legal basis should also be selected as "Traditional use registration application for a herbal medicinal product (Article 16a of Directive No 2001/83/EC)" (8);
- Where the "Authorisation procedure" (AP.12.2) is specified as "*EU authorisation procedures - Simplified registration procedure for homeopathic medicinal products*" (12) the Legal basis should also be selected as "Simplified registration application for a homeopathic medicinal product (Article 14 of Directive No 2001/83/EC)" (9).

- Where the "Authorisation procedure" (AP.12.2) is specified as *"EU other approval/authorisation procedure" (13)*, one of the below listed Legal Basis should be selected as applicable:
 - Authorisation according to Article 5(1) of Directive 2001/83/EC (12);
 - Authorisation according to Article 5(2) of Directive 2001/83/EC (13);
 - Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC (14);
 - Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC (15);
 - Available under Article 83(2) of Regulation (EC) No 726/2004 (16).

1.2.12.14. Medicinal product types (AP.12.MPT.1)

The description of the type(s) of the medicinal product must be specified based on the available values. If multiple values apply to the same AMP, then multiple values must be selected (this is repeatable field).

The following values are available:

- Authorised homeopathic medicinal product (1)
- Authorised herbal medicinal product (2)
- Parallel Distributed/Imported medicinal product (Article 76(3) and (4) of Directive No 2001/83/EC) (3)
- Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004) (4)
- Exceptional Circumstances Marketing Authorisation (Article 14 (8) of Regulation (EC) No 726/2004 or Article 22 of Directive 2001/83/EC) (5)
- Paediatric Use Marketing Authorisation (PUMA) (Article 30 of Regulation (EC) No 1901/2006) (6)
- Other (7)

The value "Other" should be specified if none of the other available values are applicable.

1.2.13. AMP - Presentation Name element structure (AP.13)

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered in the language of the country where the marketing authorisation applies in accordance with the referenced SmPC.

List of official languages per country can be found on the [Agency's website](#).

See also:

- Table 1a- Authorised Medicinal Product – language requirements; and
- Table 1b - Requirements for AMP records and attachments for countries with more than one national language for related information.

Where, in exceptional circumstances, the national SmPC for **non-centrally authorised products** (MRPs/DCPs/NAPs) is not available, a similar text (i.e. the English common text, package information

leaflet or other similar text as authorised by the Authorising Body) can be used as an attachment for the submission in the XEVMPD. The data elements AP.13.1 - AP.13.6 must however be provided in the language of the country where the marketing authorisation applies.

The data elements AP.13.1 - AP.13.6 must however be provided in the language of the country where the marketing authorisation applies.

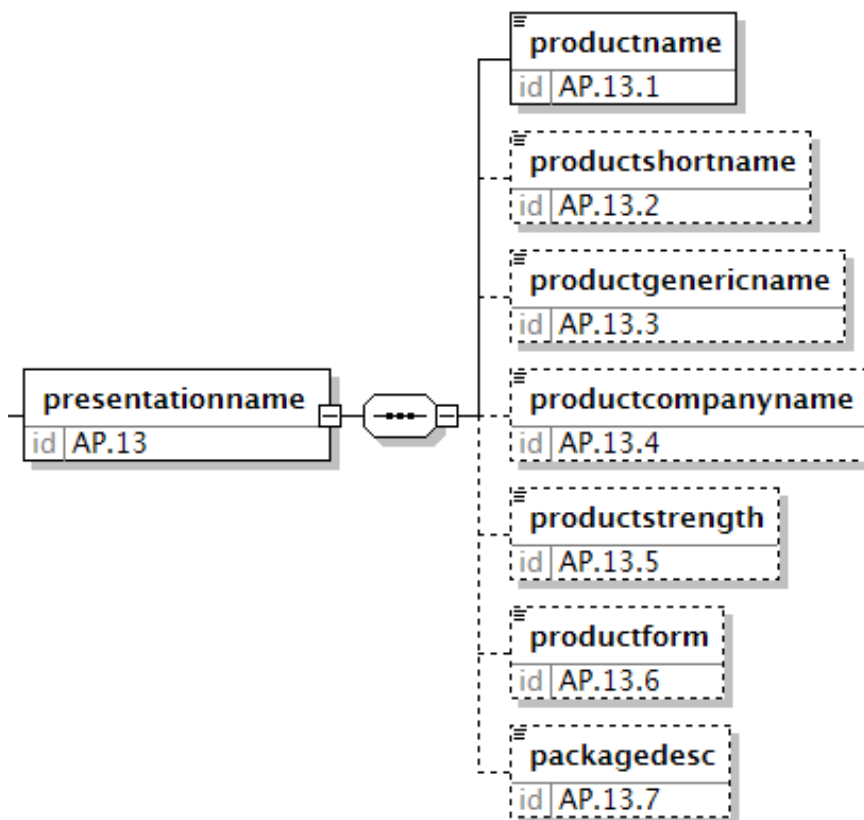
See also NOTE 15 for related information.

For **centrally authorised products**, the SmPC to be used for reference must be in English and the data elements AP.13.1 - AP.13.6 must be provided in English.

For **medicinal products authorised in Iceland, Liechtenstein and Norway in centrally authorised procedure**:

- The data elements AP.13.1 - AP.13.6 must be provided in English²;
- The SmPC of the medicinal product should be provided in English; when an SmPC or a PIL is also available in the local language this document should also be provided.

Presentation Name elements structure:



² Whilst different guidance on the provision/population of the name elements for products authorised centrally in IS/LI/NO was issued in the past, subsequent experience over time showed that the provision of the name in English is preferable in order to allow the Agency group similar CAPs based on the product name information. MAHs are not required to perform a dedicated update of their product entities to amend this information as this can be done as part of a regular maintenance.

Additional examples are also available in the '[European Medicines Agency splitting of the full presentation name of the medicinal product best practice: Procedure and principles to handle product name in the EudraVigilance Medicinal Product Dictionary \(XEVMPD\)](#)' document published in the "Data Quality-control methodology" section on the [Agency's webpage](#).

1.2.13.1. Full Presentation Name (AP.13.1)

The medicinal product name stated in Section 1. Name of the medicinal product of the corresponding SmPC must be specified.

See [EXAMPLE 12](#).

According to the QRD templates, normally the trade mark symbol is not to be included in medicinal product name stated in Section 1. Name of the medicinal product of the corresponding SmPC. However, if a trade mark symbol (e.g. ®) is included in section 1 of the SmPC, then this trade mark symbol must also be included in the medicinal product name entered in the data element AP.13.1. – see [EXAMPLE 13](#) and [EXAMPLE 16](#).

EXAMPLE 12

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

ProductXYZ 40 mg Compresse rivestite

"Full Presentation Name" (AP.13.1) = ProductXYZ 40 mg Compresse rivestite

EXAMPLE 13

The SmPC of a medicinal product authorised in Malta states the following information:

1. Name of the medicinal product

DrugABC® 40 mg tablets

"Full Presentation Name" (AP.13.1) = DrugABC® 40 mg tablets

1.2.13.2. Product Short Name (AP.13.2)

If included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, the invented (trade) name part with any other designation except the strength/pharmaceutical form must be specified.

In accordance with the definition provided in Article 1(20) of Directive 2001/83/EC, the name of the medicinal product may be an invented name - if this is the case, the invented name should be provided. See [EXAMPLE 14](#).

- If the invented name in Section 1. Name of the medicinal product of the SmPC, includes additional designations, these must also be specified.

Designations may refer to target population (e.g. adult, paediatric, children), administration device (e.g. breezehaler), potency of the product (e.g. EXTRA, FORTE, PLUS, numbers not referring to the strength), mode of action (e.g. Express), indication/intended use (e.g. Migraine), flavour/formulation part (e.g. strawberry, sugar free), time/period part (e.g. SR) etc. These designations, as well as any other qualifiers facilitating the precise identification of the product concerned for pharmacovigilance purposes must be provided in the "Product Short Name" field (AP.13.2) (e.g. Plus, Zydis) – see [EXAMPLE 15](#) and [EXAMPLE 17](#).

- If the additional designation is a number, which refers to the strength, the number referring to the strength must not be provided in the "Product Short Name" (AP.13.2) field – see [EXAMPLE 15](#).
- If the additional designation is a number, which does not refer to the strength, the number must be provided in the "Product Short Name" field (AP.13.2) – see [EXAMPLE 29](#).
- If the additional designation is a number, which refers to a ratio (e.g. in case of insulin), the number must be provided in the "Product Short Name" field (AP.13.2) if the invented name is available – see [EXAMPLE 16](#).
- If no invented (trade) name is included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, then the field "Product Short Name" (AP.13.2) must be left blank – see [EXAMPLE 19](#).

EXAMPLE 14

The SmPC of a medicinal product authorised in Malta states the following information:

1. Name of the medicinal product

ProdXYZ tablets

"Full Presentation Name" (AP.13.1) = ProdXYZ tablets

"Product Short Name" (AP.13.2) = ProdXYZ

EXAMPLE 15

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

XYZ Plus 40 Compresse rivestite

The number "40" does refer to the strength (as section 2. Qualitative and Quantitative composition of the SmPC indicates that the strength of the active ingredient is 40 mg), therefore, the following approach has to be adopted:

"Full Presentation Name" (AP.13.1) = XYZ Plus 40 Compresse rivestite

"Product Short Name" (AP.13.2) = XYZ Plus

EXAMPLE 16

The SmPC of a medicinal product authorised in Ireland states the following information:

1. Name of the medicinal product

Prodemaz® Insulin Porcine 30/70 Mix

"Full Presentation Name" (AP.13.1) = Prodemaz® Insulin Porcine 30/70 Mix

"Product Short Name" (AP.13.2) = Prodemaz 30/70 Mix

EXAMPLE 17

The SmPC of a medicinal product authorised in Malta states the following information:

1. Name of the medicinal product

ZYX Strawberry 50 mg Capsules for Children

"Full Presentation Name" (AP.13.1) = ZYX Strawberry 50 mg Capsules for Children

"Product Short Name" (AP.13.2) = ZYX Strawberry for Children

1.2.13.3. Product INN/Common Name (AP.13.3)

If the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC includes the INN/Common/Scientific name of the medicinal product, then the INN/Common/Scientific name as stated in Section 1. of the SmPC must be specified.

If the medicinal product name stated in Section 1. of the SmPC is not an invented (trade name) name, then the INN/Common/Scientific name of the medicinal product must be specified as stated in Section 1. of the SmPC with any other designation except the strength/pharmaceutical form. See [EXAMPLE 18](#).

In accordance with the definition provided in Article 1(20) of Directive 2001/83/EC, the medicinal product name may be either the INN/common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

- If no invented name is included and the name of the medicinal product stated in Section 1. Name of the medicinal product of the SmPC is the INN/common name/ scientific name accompanied by a trade mark, the INN/common name/ scientific name accompanied by a trade mark must both be provided – see [EXAMPLE 20](#).
- If no invented name is included and the name of the medicinal product stated in Section 1. Name of the medicinal product of the SmPC is the INN/common name/ scientific name accompanied by the name of the marketing authorisation holder, the INN/common name/ scientific name must be provided in this field, whereas the name of the marketing authorisation holder must be provided in the "Product Company Name" field (AP.13.4) – see [EXAMPLE 19](#).
- If no invented name is stated and the INN/common name/ scientific name in Section 1. Name of the medicinal product of the SmPC includes additional designations, these must also be specified.

Designations may refer to the target population (e.g. adult, paediatric, children), administration device, potency of the product (e.g. EXTRA, FORTE, PLUS, numbers not referring to the strength), mode of action (e.g. Express), indication/intended use (e.g. Migraine), Flavour/formulation part (e.g. strawberry, sugar free), Time/Period part (e.g. SR). These designations, as well as any other qualifiers facilitating the precise identification of the product concerned for pharmacovigilance purposes must be provided in "Product INN/Common Name" field (AP.13.3) - see [EXAMPLE 22](#).

- If the additional designation is a number, which refers to the strength, the number referring to the strength must not be provided in the "Product INN/Common Name" field (AP.13.3) - see [EXAMPLE 25](#).
- If the additional designation is a number, which does not refer to the strength, the number must be provided in the "Product INN/Common Name" field (AP.13.3) - see [EXAMPLE 26](#).
- If the additional designation is a number, which refers to a ratio (e.g. in case of insulin), the number must be provided in the "Product INN/Common Name" field (AP.13.3) - see [EXAMPLE 27](#).
- If the scientific or common (i.e. INN) name is not part of the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, then the field "Product INN/Common Name" (AP.13.3) should be left blank - see [EXAMPLE 21](#).

EXAMPLE 18

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

XYZ® (triamcinolone acetonide) 40 mg Compresse rivestite

"Full Presentation Name" (AP.13.1) = XYZ® (triamcinolone acetonide) 40 mg Compresse rivestite

"Product Short Name" (AP.13.2) = XYZ

"Product INN/Common Name" (AP.13.3) = triamcinolone acetonide

EXAMPLE 19

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

Diclofenac PharmaABC 50mg Filmtabletten

7. INHABER DER ZULASSUNG

ZPharma GmbH

"Full Presentation Name" (AP.13.1) = Diclofenac PharmaABC 50mg Filmtabletten

"Product Short Name" (AP.13.2) = <this field should be left blank>

"Product INN/Common Name" (AP.13.3) = Diclofenac

"Product Company Name" (AP.13.4) = PharmaABC

EXAMPLE 20

The SmPC of a medicinal product authorised in Ireland states the following information:

1. Name of the medicinal product

Diclofenac Dispersible PharmaK 70% w/w Gel

"Full Presentation Name" (AP.13.1) = Diclofenac Dispersible PharmaK 70% w/w Gel

"Product Short Name" (AP.13.2) = <this field should be left blank>

"Product INN/Common Name" (AP.13.3) = Diclofenac Dispersible

"Product Company Name" (AP.13.4) = PharmaK

EXAMPLE 21

The SmPC of a medicinal product authorised in the Ireland states the following information:

1. Name of the medicinal product

ProdXYZ tablets

"Full Presentation Name" (AP.13.1) = ProdXYZ tablets

"Product Short Name" (AP.13.2) = ProdXYZ

"Product INN/Common Name" (AP.13.3) = <this field should be left blank>

EXAMPLE 22

The SmPC of a medicinal product authorised in Ireland states the following information:

1. Name of the medicinal product

Ibuprofen Extra Forte 400 mg Liquid Capsules

7. Marketing Authorisation Holder

Pharma XYZ Ltd.

"Full Presentation Name" (AP.13.1) = Ibuprofen Extra Forte 400 mg Liquid Capsules

"Product Short Name" (AP.13.2) = <this field should be left blank>

"Product INN/Common Name" (AP.13.3) = Ibuprofen Extra Forte

"Product Company Name" (AP.13.4) = Pharma XYZ

1.2.13.4. Product Company Name (AP.13.4)

If included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, the Company name part of the medicinal product name without any other designations such as trade mark, strength or pharmaceutical form must be specified.

In accordance with the definition provided in Article 1(20) of Directive 2001/83/EC, the name of the medicinal product may include the name of the marketing authorisation holder. If this is the case, the exact name of the marketing authorisation holder as stated in Section 1. Name of the medicinal product of the SmPC, and as specified in the Full Presentation Name (AP.13.1) must be specified – see [EXAMPLE 23](#).

- If the company name is not included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC and the invented (trade) name is present, then the field "Product Company Name" (AP.13.4) must be left blank – see [EXAMPLE 24](#).
- If the company name is not included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC and the invented (trade) name is NOT present, then the field "Product Company Name" (AP.13.4) must be populated with the MAH name stated in Section 7. Marketing Authorisation Holder of the SmPC without the description of the legal status (e.g. Ltd, Limited, S.p.A., GmbH etc.) – see [EXAMPLE 25](#) and [EXAMPLE 26](#).
- The company name and MAH name may not be identical – see [EXAMPLE 19](#).

EXAMPLE 23

The SmPC of a medicinal product authorised in Malta states the following information:

1. Name of the medicinal product

ProductX PharmaZ capsules

"Full Presentation Name" (AP.13.1) =	ProductX PharmaZ capsules
"Product Short Name" (AP.13.2) =	ProductX
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	PharmaZ

EXAMPLE 24

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

DrugLV Filmtabletten

"Full Presentation Name" (AP.13.1) =	DrugLV Filmtabletten
"Product Short Name" (AP.13.2) =	DrugLV
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>

EXAMPLE 25

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

Amoxicillina 500 capsule

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

PharmaXYZ S.r.l.

The number "500" does refer to the strength (as section 2. Qualitative and Quantitative composition of the SmPC indicates that the strength of the active ingredient is 500 mg), therefore the following approach has to be adopted:

"Full Presentation Name" (AP.13.1) =	Amoxicillina 500 capsule
"Product Short Name" (AP.13.2) =	<this field should be left blank>
"Product INN/Common Name" (AP.13.3) =	Amoxicillina
"Product Company Name" (AP.13.4) =	PharmaXYZ
"Product Strength Name" (AP.13.5) =	500

1.2.13.5. Product Strength Name (AP.13.5)

If included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, the strength part of the medicinal product name without any other designations must be specified.

- If the strength is not included in the medicinal product name stated in section 1. Name of the medicinal product of the SmPC, then the field "Product Strength Name" (AP.13.5) must be left blank – see [EXAMPLE 28](#).
- If the strength is not included in the medicinal product name stated in section 1. Name of the medicinal product of the SmPC and a vaccine season (e.g. 2013/2014) is stated in section 1. Name of the medicinal product of the SmPC, then the field "Product Strength Name" (AP.13.5) must specify the vaccine season (e.g. 2013/2014). See [EXAMPLE 35 - Presentation name elements – vaccines](#).
- If both, the strength and the vaccine season are included in the medicinal product name stated in section 1. Name of the medicinal product of the SmPC, then the field "Product Strength Name"

(AP.13.5) must specify only the strength - see *EXAMPLE 36 - Presentation name elements – vaccines*.

- If the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC contains a number, which is not referring to the strength then the field "Product Strength Name" (AP.13.5) must be left blank – see *EXAMPLE 29*.

EXAMPLE 26

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

Triamcinolone acetoneide 40 Compresse rivestite

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

PharmaABC S.p.A.

The number "40" does not refer to the strength (as section 2. Qualitative and Quantitative composition of the SmPC indicates that the strength of the active ingredient is 150 mg), therefore, the following approach has to be adopted:

"Full Presentation Name" (AP.13.1) =	Triamcinolone acetoneide 40 Compresse rivestite
"Product Short Name" (AP.13.2) =	<this field should be left blank>
"Product INN/Common Name" (AP.13.3) =	Triamcinolone acetoneide 40
"Product Company Name" (AP.13.4) =	PharmaABC
"Product Strength Name" (AP.13.5) =	<this field should be left blank>

EXAMPLE 27

The SmPC of a medicinal product authorised in the Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

Insulin PharmaX Comb 30/70 100 I.E./ml Zylinderampullen mit Injektionssuspension

"Full Presentation Name" (AP.13.1) =	Insulin PharmaX Comb 30/70 100 I.E./ml Zylinderampullen mit Injektionssuspension
"Product Short Name" (AP.13.2) =	<this field should be left blank>
"Product INN/Common Name" (AP.13.3) =	Insulin 30/70 Comb
"Product Company Name" (AP.13.4) =	Pharma X
"Product Strength Name" (AP.13.5) =	100 I.E./ml

EXAMPLE 28

The SmPC of a medicinal product authorised in Austria states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

DrugLV Filmtabletten

"Full Presentation Name" (AP.13.1) =	DrugLV Filmtabletten
"Product Short Name" (AP.13.2) =	DrugLV
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	<this field should be left blank>

EXAMPLE 29

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

DrugVero 200 tablet Migraine, omhulde tablet

The number "200" does not refer to the strength (as section 2. Qualitative and Quantitative composition of the SmPC indicates that the strength of the active ingredient is 150 mg), therefore, the following approach has to be adopted:

"Full Presentation Name" (AP.13.1) =	DrugVero 200 tablet Migraine, omhulde tablet
"Product Short Name" (AP.13.2) =	DrugVero 200 Migraine
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	<this field should be left blank>
"Product Form Name" (AP.13.6) =	omhulde tablet

1.2.13.6. Product Form Name (AP.13.6)

If included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, the pharmaceutical form name part of the medicinal product name without any other designations must be specified.

- If the pharmaceutical form is not included in the medicinal product name stated in Section 1. Name of the medicinal product of the SmPC, then the field "Product Form Name" (AP.13.6) must be left blank – see [EXAMPLE 31](#).

EXAMPLE 30

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

XYZ® (triamcinolone acetonide) 40 mg Comprime rivestite

"Full Presentation Name" (AP.13.1) = XYZ® (triamcinolone acetonide) 40 mg Comprime rivestite
"Product Short Name" (AP.13.2) = XYZ
"Product INN/Common Name" (AP.13.3) = triamcinolone acetonide
"Product Company Name" (AP.13.4) = <this field should be left blank>
"Product Strength Name" (AP.13.5) = 40 mg
"Product Form Name" (AP.13.6) = Comprime rivestite

EXAMPLE 31

The SmPC of a medicinal product authorised in Malta states the following information:

1. Name of the medicinal product

ProductXYZ® 100mg lemon-flavour lozenges
(Pantoprazole)

"Full Presentation Name" (AP.13.1) = ProductXYZ® 100 mg lemon-flavour lozenges Pantoprazole
"Product Short Name" (AP.13.2) = ProductXYZ lemon-flavour
"Product INN/Common Name" (AP.13.3) = Pantoprazole
"Product Company Name" (AP.13.4) = <this field should be left blank>
"Product Strength Name" (AP.13.5) = 100mg
"Product Form Name" (AP.13.6) = lozenges

EXAMPLE 32

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

ProduktG PharmaS 10 mg

"Full Presentation Name" (AP.13.1) = ProduktG PharmaS 10 mg
"Product Short Name" (AP.13.2) = ProduktG
"Product INN/Common Name" (AP.13.3) = <this field should be left blank>
"Product Company Name" (AP.13.4) = PharmaS
"Product Strength Name" (AP.13.5) = 10 mg
"Product Form Name" (AP.13.6) = <this field should be left blank>

EXAMPLE 33 - Presentation name elements – vaccines

The SmPC of a medicinal product with a valid MA in Northern Ireland states the following information:

1. Name of the medicinal product

VACCXYZ 10 microgram/strain suspension for injection; Influenza vaccine (split virion, inactivated)

"Full Presentation Name" field (AP.13.1) = VACCXYZ 10 microgram/strain suspension for injection;
Influenza vaccine (split virion, inactivated)
"Product Short Name" field (AP.13.2) = VACCXZ
"Product INN/Common Name" field (AP.13.3) = Influenza vaccine (split virion, inactivated)
"Product Company Name" field (AP.13.4) = <this field should be left blank>
"Product Strength Name" field (AP.13.5) = 10 microgram/strain
"Product Form Name" field (AP.13.6) = suspension for injection

EXAMPLE 34 - Presentation name elements – vaccines

The SmPC of a medicinal product authorised in Ireland states the following information:

1. Name of the medicinal product

ProductX suspension and emulsion for emulsion for injection

Influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)

"Full Presentation Name" field (AP.13.1) = ProductX suspension and emulsion for emulsion for
injection Influenza vaccine (H1N1) (split virion,
inactivated, adjuvanted)
"Product Short Name" field (AP.13.2) = ProductX
"Product INN/Common Name" field (AP.13.3) = Influenza vaccine (H1N1) (split virion, inactivated,
adjuvanted)
"Product Company Name" field (AP.13.4) = <this field should be left blank>
"Product Strength Name" field (AP.13.5) = <this field should be left blank>
"Product Form Name" field (AP.13.6) = suspension and emulsion for emulsion for injection

EXAMPLE 35 - Presentation name elements – vaccines

The SmPC of a medicinal product authorised In Ireland states the following information:

1. Name of the medicinal product

DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)

"Full Presentation Name" field (AP.13.1) = DrugABC 2013/2014 suspension for injection (influenza
vaccine, surface antigen, inactivated)
"Product Short Name" field (AP.13.2) = DrugABC
"Product INN/Common Name" field (AP.13.3) = influenza vaccine, surface antigen, inactivated

"Product Company Name" field (AP.13.4) = <this field should be left blank>
 "Product Strength Name" field (AP.13.5) = 2013/2014
 "Product Form Name" field (AP.13.6) = suspension for injection

EXAMPLE 36 - Presentation name elements – vaccines

The SmPC of a medicinal product authorised In Ireland states the following information:

1. Name of the medicinal product

DrugABC 2013/2014 10 microgram/strain suspension for injection
 (influenza vaccine, surface antigen, inactivated)

"Full Presentation Name" field (AP.13.1) = DrugABC 2013/2014 10 microgram/strain suspension for injection (influenza vaccine, surface antigen, inactivated)
 "Product Short Name" field (AP.13.2) = DrugABC
 "Product INN/Common Name" field (AP.13.3) = influenza vaccine, surface antigen, inactivated
 "Product Company Name" field (AP.13.4) = <this field should be left blank>
 "Product Strength Name" field (AP.13.5) = 10 microgram/strain
 "Product Form Name" field (AP.13.6) = suspension for injection

1.2.14. Authorised pharmaceutical form (AP.APT.1)

The authorised pharmaceutical form(s) must be specified as indicated in the section 3. Pharmaceutical Form of the SmPC.

"Authorised pharmaceutical form" can be defined as the pharmaceutical form of the product as it is authorised and, where applicable, before transformation into the administrable pharmaceutical form.

The pharmaceutical form stated in section 3. Pharmaceutical Form of the SmPC may differ from the standard term included in the EDQM standard term list. In such cases, the EDQM standard term available in the XEVMPD must be selected (i.e. it is not necessary to enter a new proposed term for the pharmaceutical form stated in section 3. Pharmaceutical Form of the SmPC) – see *EXAMPLE 37, scenario 1*.

- If the **standard term** of the requested pharmaceutical form **is available** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms"), MAH should use such standard term in their pharmaceutical product entity within their AMP.
- If the required pharmaceutical form **is NOT available as a standard term but is available as a proposed term** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms"), MAH should use such proposed term in their pharmaceutical product entity within their AMP.

- If the pharmaceutical form **is not available as a standard or a proposed term** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms*"), and:
 - the term is flagged as "Pending" on the [EDQM website](#) and it is not flagged as "Nullified" in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#); or
 - an application for a new pharmaceutical form was/will be submitted to the maintenance Organisation (i.e. EDQM) in the NCA or EMA (as applicable) with the request of adding it to the standard term list; and
 - the requested pharmaceutical form **is not included in the list of proposed pharmaceutical forms re-mapped to standard pharmaceutical forms** in the spread sheet "**Re-mapped_PDFs**" published in the Controlled Vocabulary (CV) list "*eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms*", available at the [Agency's website](#);

the pharmaceutical form must be provided as a **new proposed term** in the XEVPRM.

See section [1.8. Initial submission of an authorised/administrable pharmaceutical form](#) of this document for further information on how to submit a pharmaceutical form in the XEVMPD.

NOTE 7

In case multiple distinct pharmaceutical forms as indicated in section 3. Pharmaceutical Form of the SmPC can be coded with individual (EDQM) Standard Pharmaceutical Form EV Code (available in the XEVMPD look-up table/ Controlled Vocabulary (CV) list "*eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms*", published at the [Agency's website](#)), the authorised pharmaceutical form must be provided for each distinct pharmaceutical form (i.e. repeat the authorised pharmaceutical form data element).

EXAMPLE 37

Scenario 1

Section 3. PHARMACEUTICAL FORM of the SmPC states:

Hard capsule.

Cream.

Therefore, **two** Authorised pharmaceutical forms must be specified:

- Capsule, hard (PHF00006MIG)
- Cream (PHF00017MIG)

Scenario 2

Section 3. PHARMACEUTICAL FORM of the SmPC states:

Tablet and gel

Therefore, **two** Authorised pharmaceutical forms must be specified:

- Tablet (PHF00245MIG)

NOTE 8

Where the medicinal product contains an authorised pharmaceutical form to be reconstituted or diluted prior to administration, the authorised pharmaceutical form should be specified as a single value and as it is described in section 3. Pharmaceutical form of the SmPC.

- E.g. "Powder for solution for injection" is the authorised pharmaceutical form, for which the administrable pharmaceutical form is "Solution for injection".

Where the medicinal product contains an authorised pharmaceutical form for which no reconstitution, dilution or transformation is necessary prior administration, the authorised pharmaceutical form should be specified as a single value and as it is described in section 3. Pharmaceutical form of the SmPC.

- E.g. "Film-coated tablet" is the authorised pharmaceutical form, for which the administrable pharmaceutical form is "Film-coated tablet".

1.2.15. Package description (AP.13.7)

A brief package description of the pack size(s) corresponding to the referenced authorisation number as stated in section 6.5 Nature and contents of container of the SmPC may be specified in the language of the SmPC. An English text is also acceptable.

Mandatory provision of pack size information and the information on the product down to the pack size level have been deferred to until ISO IDMP standards implementation.

The package description is a textual representation mainly in relation to the pack size(s).

EXAMPLES of package description:

84 or 100 tablets in an amber glass bottle.

48 or 96 tablets in an aluminium blister pack.

Packs containing 7, 14, 28, 42, 56, 84 and 98 film-coated tablets.

Pack sizes of 1 and 5 inls of 10 ml or a multipack of 5 packs of 1 x 10 ml inl.

Confezione da 14, 28 or 98 compresse rivestite con film in blister

Velikost balení: 20 tablet

Ampoule en verre neutre de 1 ml. 5 ampoules dans un carton.

- For non-centrally authorised products, one authorisation number can be applicable to several pack sizes. The MAH may wish to make either:
 - one XEVMPD product entity with a brief description of all pack sizes (separated by a comma) in the "Package description" field (AP.13.7) – see EXAMPLE 2; or
 - multiple XEVMPD product entities each referencing an individual pack size in the "Package description" field (AP.13.7) – see EXAMPLE 3.
- For centrally authorised products, each presentation is authorised with an individual authorisation number. Therefore, individual AMP entities must be submitted for each pack size – see EXAMPLE 6.

1.2.16. Comment (AP.14)

The text in English "Medicinal product authorised for the treatment in children" must be stated if an indication for pediatric population (children under the age of 18) is stated in Section 4.1 Therapeutic indications of the SmPC and/or a posology is stated for any subset of the pediatric population in Section 4.2. Posology and method of administration of the SmPC.

In case of a nullification [i.e. operation type 'Nullification' (4) is used in an XEVPRM] of an authorised medicinal product entity, the 'Comment' field (AP.14) must be populated with the reason for nullification (e.g. "Duplicate of PRDXXX). See [Process map 13 – Nullification of an AMP](#) entity

of this document for further information.

- Authorised Medicinal Product entity flagged as "Valid" by the Agency can only be nullified by the Agency. See section [2.4.7. Nullification of AMP entities](#) of this document for further information.

EXAMPLE 38

Scenario 1

Section 4.1 Therapeutic indications of the SmPC states:

Levetiracetam ProductXYZ is indicated as monotherapy in the treatment of partial onset seizures in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

Scenario 2

Section 4.2 Posology and method of administration of the SmPC states:

Posology

Monotherapy for adults and adolescents from 16 years of age.

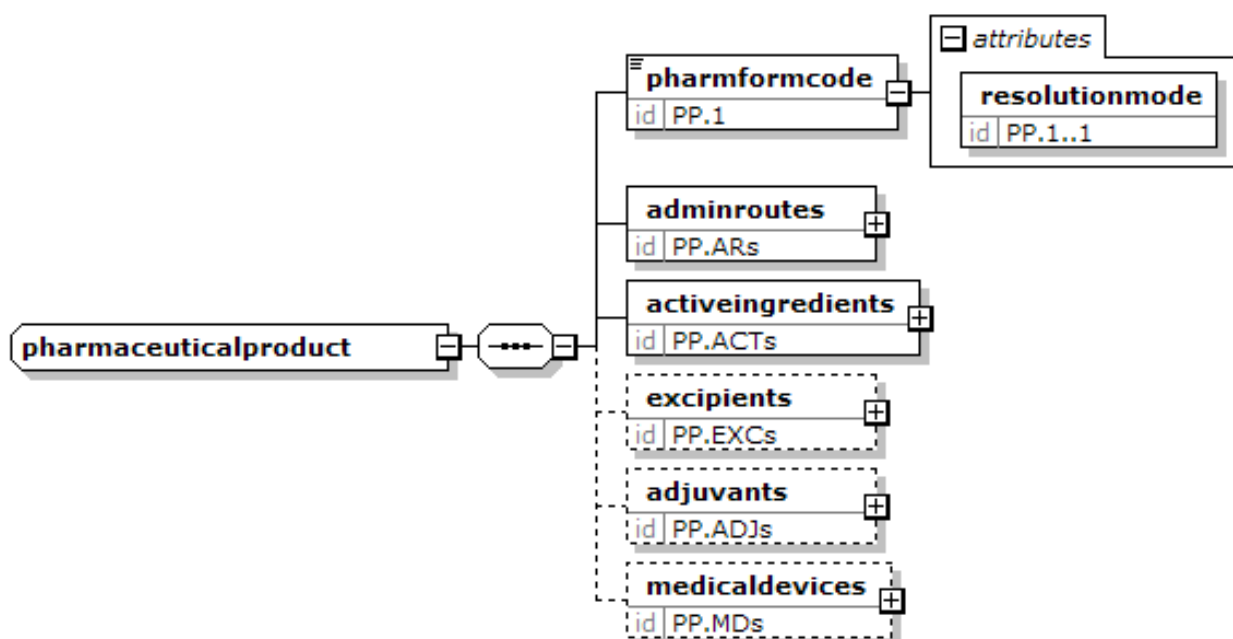
The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks.

Therefore, in both cases, the text in English "Medicinal product authorised for the treatment in children" must be specified in the "Comment" field (AP.14) of the authorised medicinal product entity.

1.2.17. AMP - Pharmaceutical product elements (AP.PPs)

Section 3. Pharmaceutical form and section 2. Qualitative and Quantitative composition of the SmPC indicate the number and composition of pharmaceutical product(s) within the medicinal product.

Pharmaceutical product element structure:



Each Authorised Medicinal Product entity in the XEVMPD must contain at least one pharmaceutical product. The technical concept of a "pharmaceutical product" refers to the qualitative and quantitative composition of a medicinal product in the pharmaceutical form approved for administration in line with the regulated product information.

A medicinal product may contain one or more "pharmaceutical product" (e.g. a kit containing vaginal tablets 500 mg and a vaginal cream 10% or a kit containing a combination of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets). In these instances, a pharmaceutical product section is to be completed for each "pharmaceutical product" in an XEVPRM – see [EXAMPLE 40](#) and [EXAMPLE 41](#).

Where applicable, the technical concept of a "pharmaceutical product" can also include information on a medical device if it is an "integral part" of the medicinal product for example the scaffolding or net for a cell therapy medicinal product in accordance with Regulation (EC) No 1394/2007.

The administrable pharmaceutical form refers to the pharmaceutical form for administration to the patient, after any necessary transformation of the "manufactured" pharmaceutical form has been carried out.

EXAMPLE 39

TradenameXYZ® powder and solvent for solution for injection

Authorised pharmaceutical form: powder and solvent for solution for injection

Administrable Pharmaceutical product (after transformation) – administrable pharmaceutical form: solution for injection

EXAMPLE 40

The SmPC of a medicinal product authorised In Ireland states the following information:

1. Name of the medicinal product

ProductQ Combi Pessary and Cream

2. Qualitative and Quantitative composition

ProductQ Combi pessary contains Clotrimazole 500mg.

ProductQ Combi cream contains Clotrimazole 2% w/w.

For excipients, see 6.1.

3. Pharmaceutical form

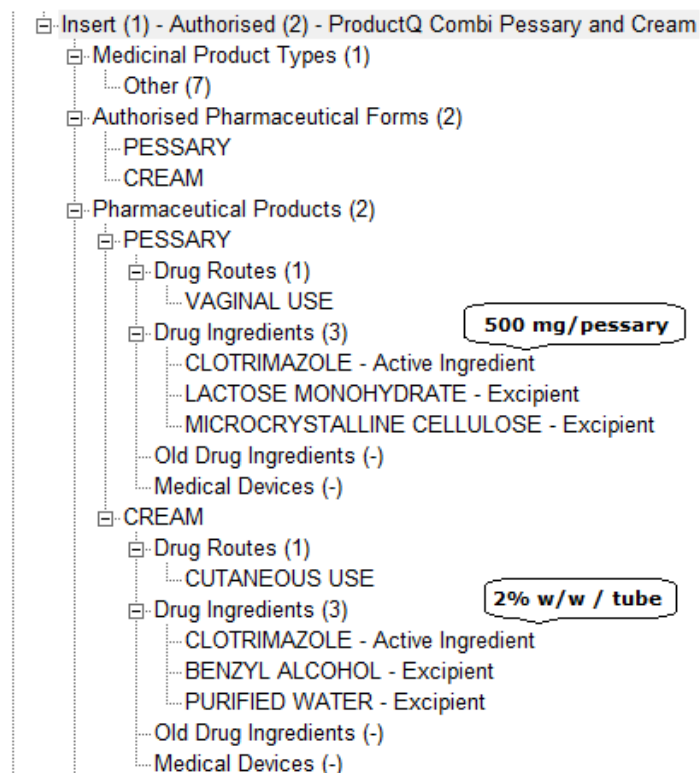
Pessary and Cream

6.1 List of excipients

The pessary contains: Lactose monohydrate, Microcrystalline cellulose;

The cream contains: Benzyl alcohol, Purified Water

An XEVMPD entity should be created by **EVWEB users** as follows:



XEVMPD entity should be created by **Gateway users** as follows:

SmPC Reference	XEVRM Technical Specifications		xEVMPD Unit Code/Value
Section 1		Authorised Product – Presentation Name element AP.13 presentationname	
	AP.13.1	Productname	ProductQ Combi Pessary and Cream
	AP.13.2	Productshortname	ProductQ Combi
	AP.13.3	Productgenericname	
	AP.13.4	Productcompanyname	
	AP.13.5	Productstrength	
	AP.13.6	Productform	Pessary and Cream
		Authorisation – Medicinal Product Type elements AP.12.MPT medicinalproducttype	
	AP.12.MPT.1	producttypecode	7 (= Other)
		Authorised product - Authorised Pharmaceutical Form elements AP.APF authpharmform	
Section 3. Pharmaceutical Form	AP.APF.1	authpharmformcode	PHF00180MIG [= Pessary]
	@ AP.APF..1	resolutionmode	2
Section 3		The Pharmaceutical Product element PP pharmaceuticalproduct	
	PP.1	pharmformcode	PHF00180MIG [= Pessary]
	@PP.1..1	(@)resolutionmode	2
Section 4.2		The Pharmaceutical Product – Administration Route element PP.AR adminroute	
	PP.AR.1	adminroutecode	ADR00067MIG [= vaginal use]
	@ PP.AR.1..1	(@)resolutionmode	2
Section 2		The Pharmaceutical Product – Active Ingredient element PP.ACT activeingredient	
Section 2	PP.ACT.1	substancecode	SUB06777MIG [=clotrimazole]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]

SmPC Reference	XEVRM Technical Specifications		xEVMPD Unit Code/Value
	PP.ACT.3	lowamountnumervalue	500
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{PESSARY} [=Pessary]
Section 6.1		The Pharmaceutical product – Excipient element PP.EXC excipient	
Section 6.1	PP.EXC.1	substancecode	SUB12098MIG [= Lactose monohydrate]
	@ PP.EXC.1..1	(@)resolutionmode	2
Section 6.1	PP.EXC.1	substancecode	SUB12626MIG [=Microcrystalline cellulose]
	@ PP.EXC.1..1	(@)resolutionmode	2
		Authorised product - Authorised Pharmaceutical Form elements AP.APF authpharmform	
Section 3. Pharmaceutical Form	AP.APF.1	authpharmformcode	PHF00017MIG [=cream]
	@ AP.APF..1	resolutionmode	2
Section 3		The Pharmaceutical Product element PP pharmaceuticalproduct	
	PP.1	pharmformcode	PHF00017MIG [=cream]
	@PP.1..1	(@)resolutionmode	2
Section 4.2		The Pharmaceutical Product – Administration Route element PP.AR adminroute	
	PP.AR.1	adminroutecode	ADR00003MIG [= cutaneous use]
	@ PP.AR.1..1	(@)resolutionmode	2
Section 2		The Pharmaceutical Product – Active Ingredient element PP.ACT activeingredient	
Section 2	PP.ACT.1	substancecode	SUB06777MIG [=clotrimazole]

SmPC Reference	XEVRM Technical Specifications		xEVMPD Unit Code/Value
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]
	PP.ACT.3	lowamountnumervalue	2
	PP.ACT.4	lowamountnumerprefix	
	PP.ACT.5	lowamountnumerunit	%{W/W} [=Percent Weight/Weight]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TUBE} [= Tube]
Section 6.1		The Pharmaceutical product – Excipient element <i>PP.EXC excipient</i>	
Section 6.1	PP.EXC.1	substancecode	SUB057771MIG [= Benzyl Alcohol]
	@ PP.EXC.1..1	(@)resolutionmode	2
Section 6.1	PP.EXC.1	substancecode	SUB33563 [= Purified Water]
	@ PP.EXC.1..1	(@)resolutionmode	2

EXAMPLE 41

The SmPC of a medicinal product authorised In Ireland states the following information:

1. Name of the medicinal product

TriProduct contraceptive tablets

2. Qualitative and Quantitative composition

White tablets: Ethinylestradiol 0.5 mg; Norethindrone 0.035 mg

Peach tablets: Ethinylestradiol 0.75 mg; Norethindrone 0.035 mg

Pink tablets: Ethinylestradiol 1 mg; Norethindrone 0.035 mg

3. Pharmaceutical form

Tablets (white, peach, pink)

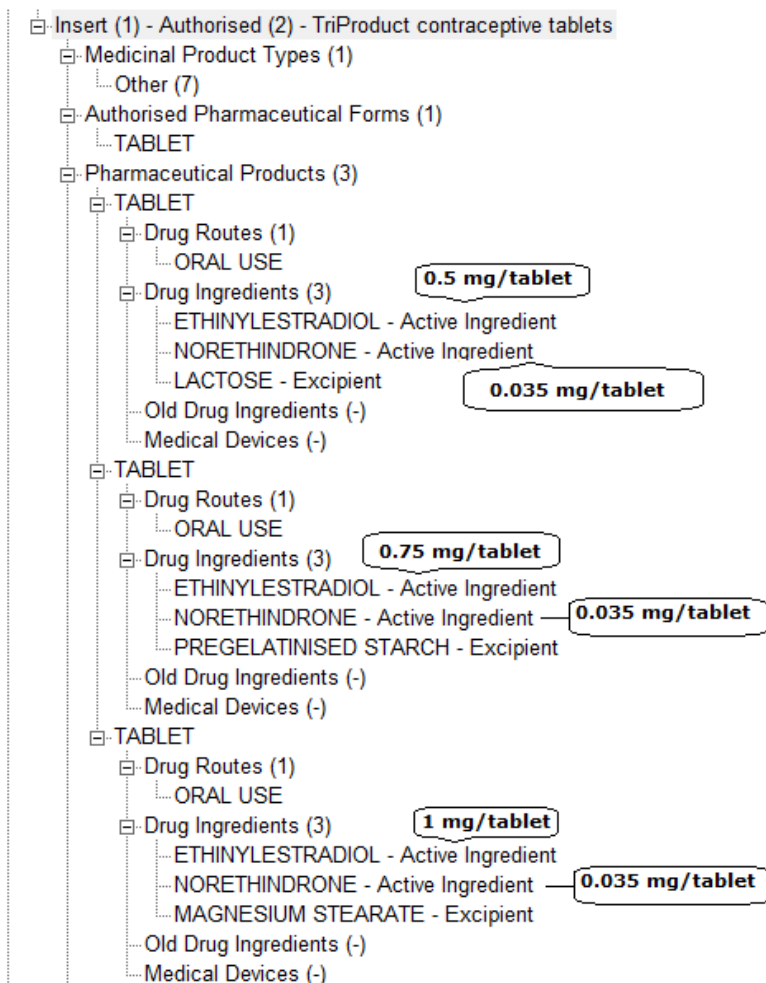
6.1 List of excipients

White tablets: Lactose

Peach tablet: Pregelatinised starch

Pink tablet: Magnesium stearate

An XEVMPD entity should be created by **EVWEB users** as follows:



XEVMPD entity should be created by **Gateway users** as follows:

SmPC Reference	XEVPRM Technical Specifications		XEVMPD Unit Code/Value
Section 1		Elements within the Authorised Product – Presentation Name element AP.13 presentationname	
	AP.13.1	Productname	Triproduct contraceptive tablets
	AP.13.2	Productshortname	Triproduct
	AP.13.3	Productgenericname	
	AP.13.4	Productcompanyname	
	AP.13.5	Productstrength	

SmPC Reference	XEVPRM Technical Specifications		XEVMPD Unit Code/Value
	AP.13.6	Productform	tablets
		Authorisation – Medicinal Product Type elements AP.12.MPT medicinalproducttype	
	AP.12.MPT.1	producttypecode	7 (= Other)
		Authorised product - Authorised Pharmaceutical Form elements AP.APF authpharmform	
Section 3. Pharmaceutical Form	AP.APF.1	authpharmformcode	PHF00245MIG [= tablet]
	@ AP.APF..1	resolutionmode	2
Section 3		The Pharmaceutical Product element PP pharmaceuticalproduct	
	PP.1	pharmformcode	PHF00245MIG [= tablet]
	@PP.1..1	(@)resolutionmode	2
Section 4.2		The Pharmaceutical Product – Administration Route element PP.AR adminroute	
	PP.AR.1	adminroutecode	ADR00048MIG [= oral use]
	@ PP.AR.1..1	(@)resolutionmode	2
Section 2		The Pharmaceutical Product – Active Ingredient element PP.ACT activeingredient	
Section 2	PP.ACT.1	substancecode	SUB07277MIG [= Ethinylestradiol]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]
	PP.ACT.3	lowamountnumervalue	0.5
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
Section 2	PP.ACT.1	substancecode	SUB09362MIG [= Norethindrone]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]

SmPC Reference	XEVPRM Technical Specifications		XEVMPD Unit Code/Value
	PP.ACT.3	lowamountnumervalue	0.035
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
Section 6.1		The Pharmaceutical product – Excipient element <i>PP.EXC excipient</i>	
Section 6.1	PP.EXC.1	substancecode	SUB14317MIG [= Lactose]
	@ PP.EXC.1..1	(@)resolutionmode	2
Section 3		The Pharmaceutical Product element <i>PP pharmaceuticalproduct</i>	
	PP.1	pharmformcode	PHF00245MIG [= tablet]
	@PP.1..1	(@)resolutionmode	2
Section 4.2		The Pharmaceutical Product – Administration Route element <i>PP.AR adminroute</i>	
	PP.AR.1	adminroutecode	ADR00048MIG [= oral use]
	@ PP.AR.1..1	(@)resolutionmode	2
Section 2		The Pharmaceutical Product – Active Ingredient element <i>PP.ACT activeingredient</i>	
Section 2	PP.ACT.1	substancecode	SUB07277MIG [=Ethinylestradiol]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]
	PP.ACT.3	lowamountnumervalue	0.75
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
Section 2	PP.ACT.1	substancecode	SUB09362MIG [= Norethindrone]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]
	PP.ACT.3	lowamountnumervalue	0.035

SmPC Reference	XEVRM Technical Specifications		XEVMPD Unit Code/Value
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
Section 6.1		The Pharmaceutical product – Excipient element <i>PP.EXC excipient</i>	
Section 6.1	PP.EXC.1	substancecode	SUB37204MIG [= Pregelatinised starch]
	@ PP.EXC.1..1	(@)resolutionmode	2
Section 3		The Pharmaceutical Product element <i>PP pharmaceuticalproduct</i>	
	PP.1	pharmformcode	PHF00245MIG [= tablet]
	@PP.1..1	(@)resolutionmode	2
Section 4.2		The Pharmaceutical Product – Administration Route element <i>PP.AR adminroute</i>	
	PP.AR.1	adminroutecode	ADR00048MIG [= oral use]
	@ PP.AR.1..1	(@)resolutionmode	2
Section 2		The Pharmaceutical Product – Active Ingredient element <i>PP.ACT activeingredient</i>	
Section 2	PP.ACT.1	substancecode	SUB07277MIG [= Ethinylestradiol]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]
	PP.ACT.3	lowamountnumervalue	0.75
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
	PP.ACT.14	highamountdenomunit	
Section 2	PP.ACT.1	substancecode	SUB09362MIG [= Norethindrone]
	@ PP.ACT.1..1	(@)resolutionmode	2
	PP.ACT.2	concentrationtypecode	1 [= Equal]

SmPC Reference	XEVRM Technical Specifications		XEVRM Unit Code/Value
	PP.ACT.3	lowamountnumervalue	0.035
	PP.ACT.4	lowamountnumerprefix	M [= milli (1x10 ⁻³)]
	PP.ACT.5	lowamountnumerunit	G [= Gram(s)]
	PP.ACT.6	lowamountdenomvalue	1
	PP.ACT.7	lowamountdenomprefix	1 [= single]
	PP.ACT.8	lowamountdenomunit	1{TABLET} [= Tablet]
Section 6.1		The Pharmaceutical product – Excipient element <i>PP.EXC excipient</i>	
Section 6.1	PP.EXC.1	substancecode	SUB12527MIG [= Magnesium stearate]
	@ PP.EXC.1..1	(@)resolutionmode	2

1.2.17.1. Administrable pharmaceutical form (PP.1)

The administrable pharmaceutical form(s) must be specified in accordance with Section 3. Pharmaceutical form of the SmPC.

The pharmaceutical form stated in section 3. Pharmaceutical Form of the SmPC may differ from the standard term included in the EDQM standard term list. In such cases, the EDQM standard term available in the XEVRM must be selected (i.e. it is not necessary to enter a new proposed term for the pharmaceutical form stated in section 3. Pharmaceutical Form of the SmPC) – see [EXAMPLE 37, scenario 1](#).

The "*Administrable pharmaceutical form*" refers to the pharmaceutical form for administration to the patient, after any necessary transformation of the authorised pharmaceutical form has been carried out.

[EXAMPLES](#) of administrable pharmaceutical forms identical to the authorised pharmaceutical forms: solution for injection, tablet, capsule, inhalation powder.

The administrable pharmaceutical form is identical to the authorised pharmaceutical form in cases where no transformation is necessary prior administration to the patient.

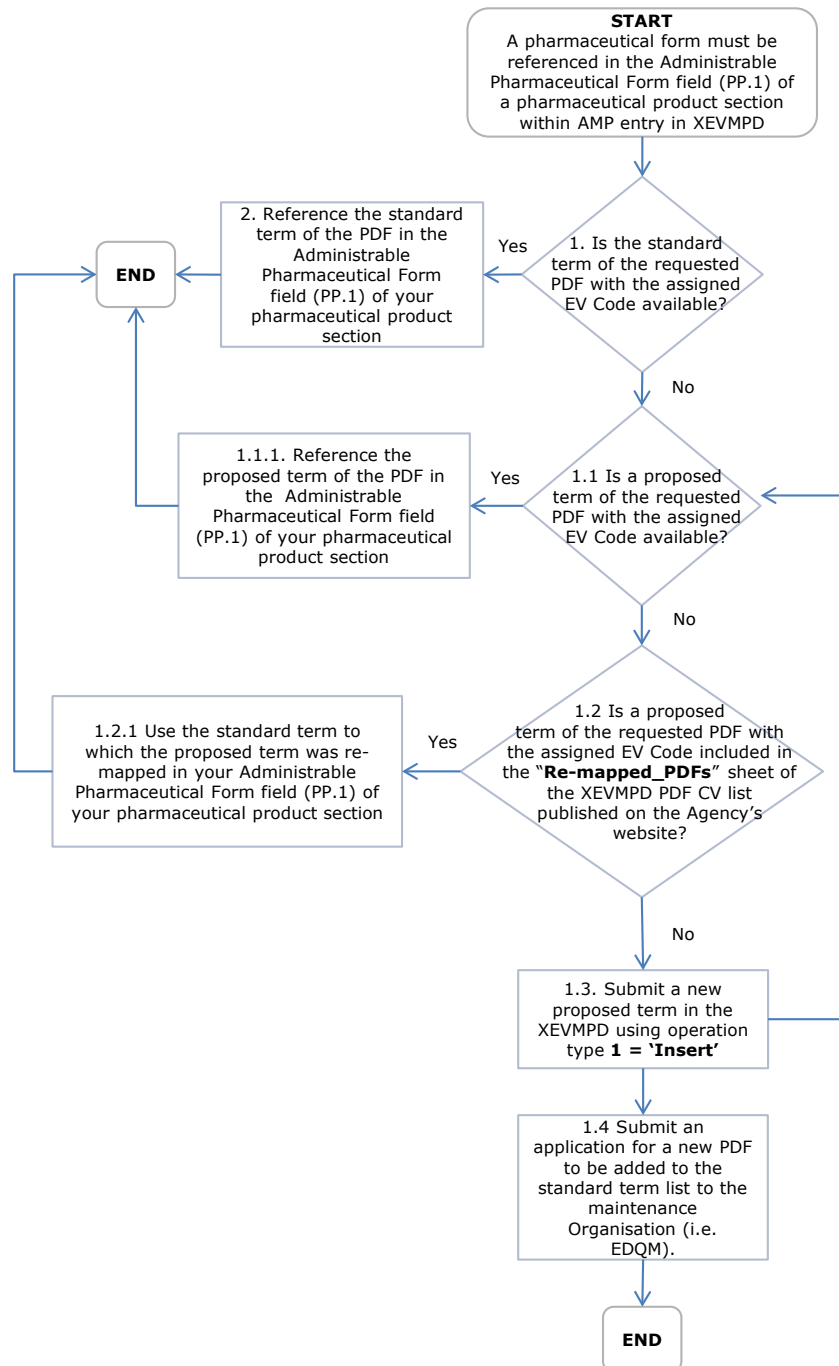
- If the **standard term** of the requested administrable pharmaceutical form **is available** in the XEVRM Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudragil Product Dictionary (XEVRM) pharmaceutical dose forms*"), MAH should use such standard term in their pharmaceutical product entity within their AMP.
- If the required pharmaceutical form **is NOT available as a standard term but is available as a proposed term** in the XEVRM Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudragil Product Dictionary (XEVRM) pharmaceutical dose forms*"), MAH should use such proposed term in their pharmaceutical product entity within their AMP.

- If the pharmaceutical form **is not available as a standard or proposed term** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms*"), and:
 - the term is flagged as "Pending" on the [EDQM website](#) and it is not flagged as "Nullified" in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#); or
 - where an application for a new pharmaceutical form was/will be submitted to the maintenance Organisation (i.e. EDQM) in the NCA or EMA (as applicable) with the request of adding it to the standard term list; and
 - the requested pharmaceutical form **is not included in the list of proposed pharmaceutical forms re-mapped to standard pharmaceutical forms** in the spread sheet "**Re-mapped_PDFs**" published in the Controlled Vocabulary (CV) list "*eXtended Eudravigilance Product Dictionary (XEVMPD) pharmaceutical dose forms*", available at the [Agency's website](#);

the pharmaceutical form can be provided as a **new proposed term** in the XEVPRM.

See section [1.8. Initial submission of an authorised/administrable pharmaceutical form](#) of this document for further information on how to submit a pharmaceutical form in the XEVMPD.

Process map 1 - Referencing administrable pharmaceutical form in a pharmaceutical product



1.2.17.2. Administration route (PP.AR.1)

The route of administration of the pharmaceutical form must be specified in accordance with Section 4.2. Posology and method of administration of the SmPC.

Administration route section describes the route(s) of administration i.e. the path by which the medicinal product (described as technical concept of a "pharmaceutical product") is taken into or makes contact with the body. The route of administration should be described as reflected in section 4.2 Posology and Method of Administration of the SmPC.

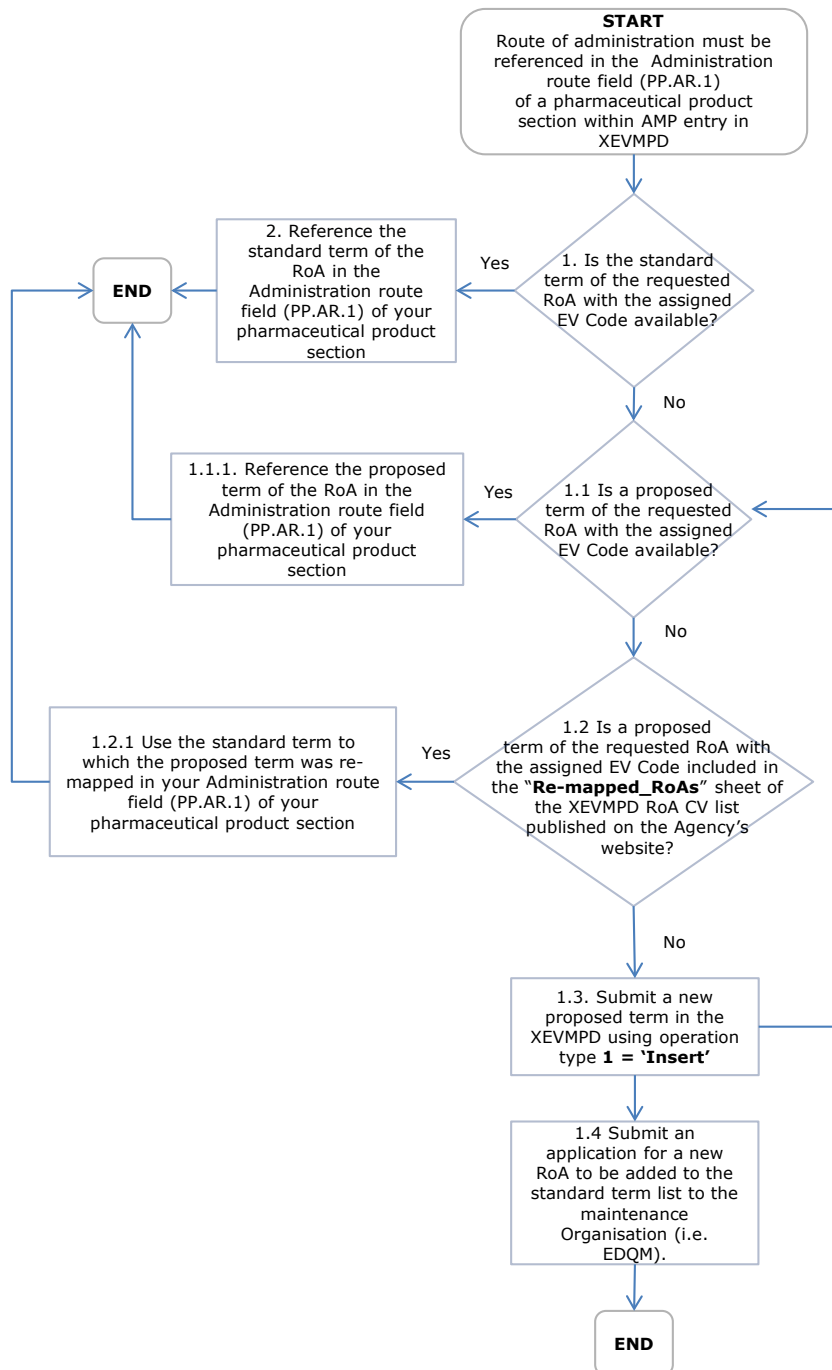
EXAMPLES of routes of administration: oral use, intravenous use, oromucosal use, ocular use

- MAHs may reference deprecated route of administration in Authorised Medicinal Products to facilitate the Article 57(2) electronic submission of information on medicines.
- If the **standard term** of the route of administration **is available** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudravigilance Product Dictionary (XEVMPD) routes of administration*"), MAH should use such standard term in their pharmaceutical product entity within their AMP.
- If the route of administration **is NOT available as a standard term but is available as a proposed term** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) (see "*eXtended Eudravigilance Product Dictionary (XEVMPD) routes of administration*"), MAH should use such proposed term in their pharmaceutical product entity within their AMP.
- If the route of administration **is not available as a standard or proposed term** in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#) see "*eXtended Eudravigilance Product Dictionary (XEVMPD) routes of administration*", and
 - the term is flagged as "Pending" on the [EDQM website](#) and it is not flagged as "Nullified" in the XEVMPD Lookup table/Controlled Vocabulary (CV) list published on the [Agency's website](#); or
 - where an application for a new route of administration was/will be submitted to the maintenance Organisation (i.e. EDQM) with the request of adding it to the standard term list; and
 - the requested route of administration **is not included in the list of proposed routes of administration re-mapped to Standard routes of administration** in the spread sheet "**Re-mapped_RoAs**" of the published Controlled Vocabulary (CV) list "*eXtended Eudravigilance Product Dictionary (XEVMPD) routes of administration*", available at the [Agency's website](#);

the route of administration should be provided as a **new proposed term** in the XEVPRM.

See section [1.9. Initial Submission of a route of administration \(RoA\)](#) of this document for further information on how to submit a RoA in the XEVMPD.

Process map 2 - Referencing route of administration in a pharmaceutical product



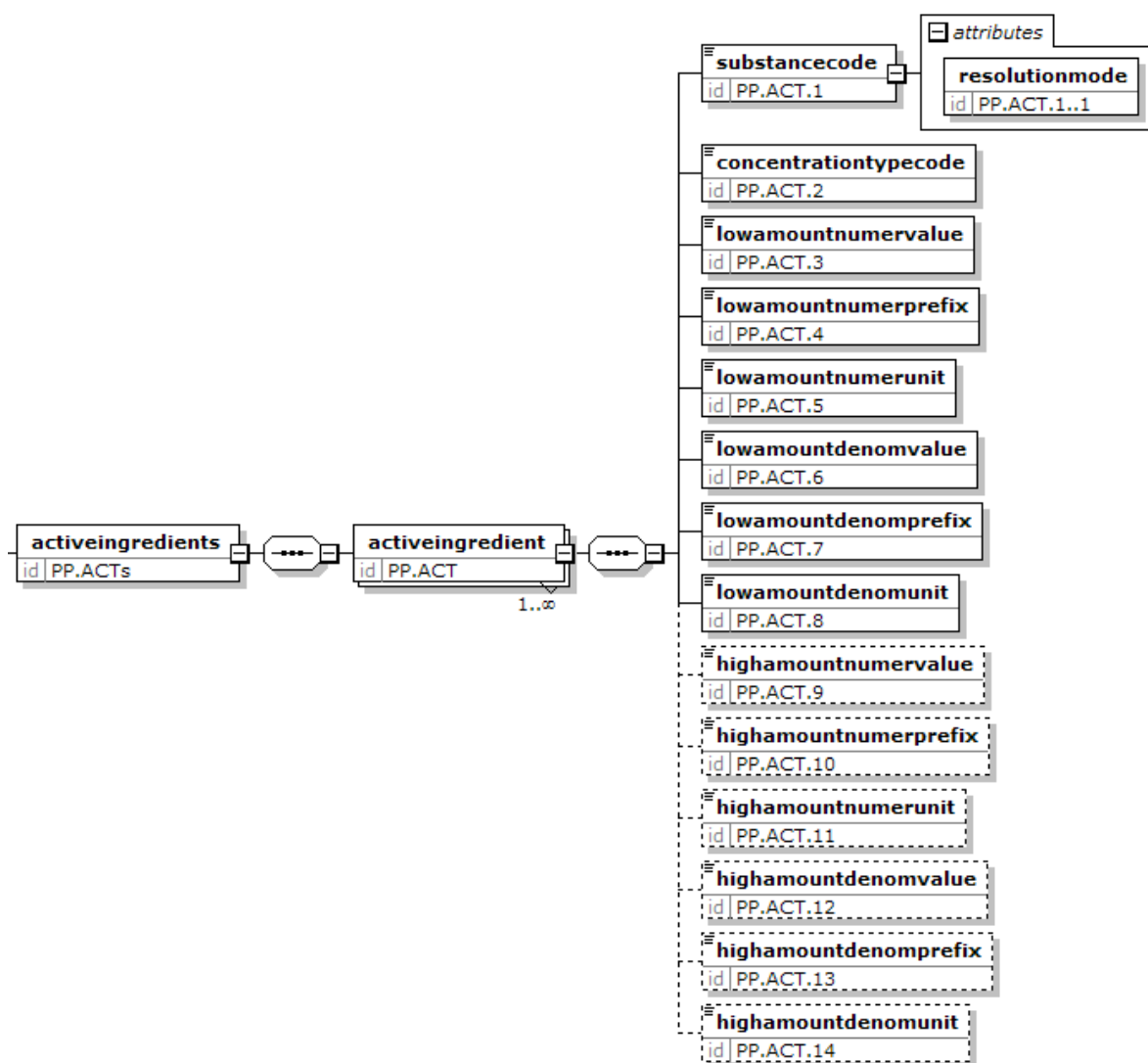
1.2.17.3. Pharmaceutical product drug ingredients and medical device(s)

Section 2. Qualitative and Quantitative composition of the SmPC and section 6.1. List of excipients of the SmPC indicate the composition of pharmaceutical product(s) within the medicinal product.

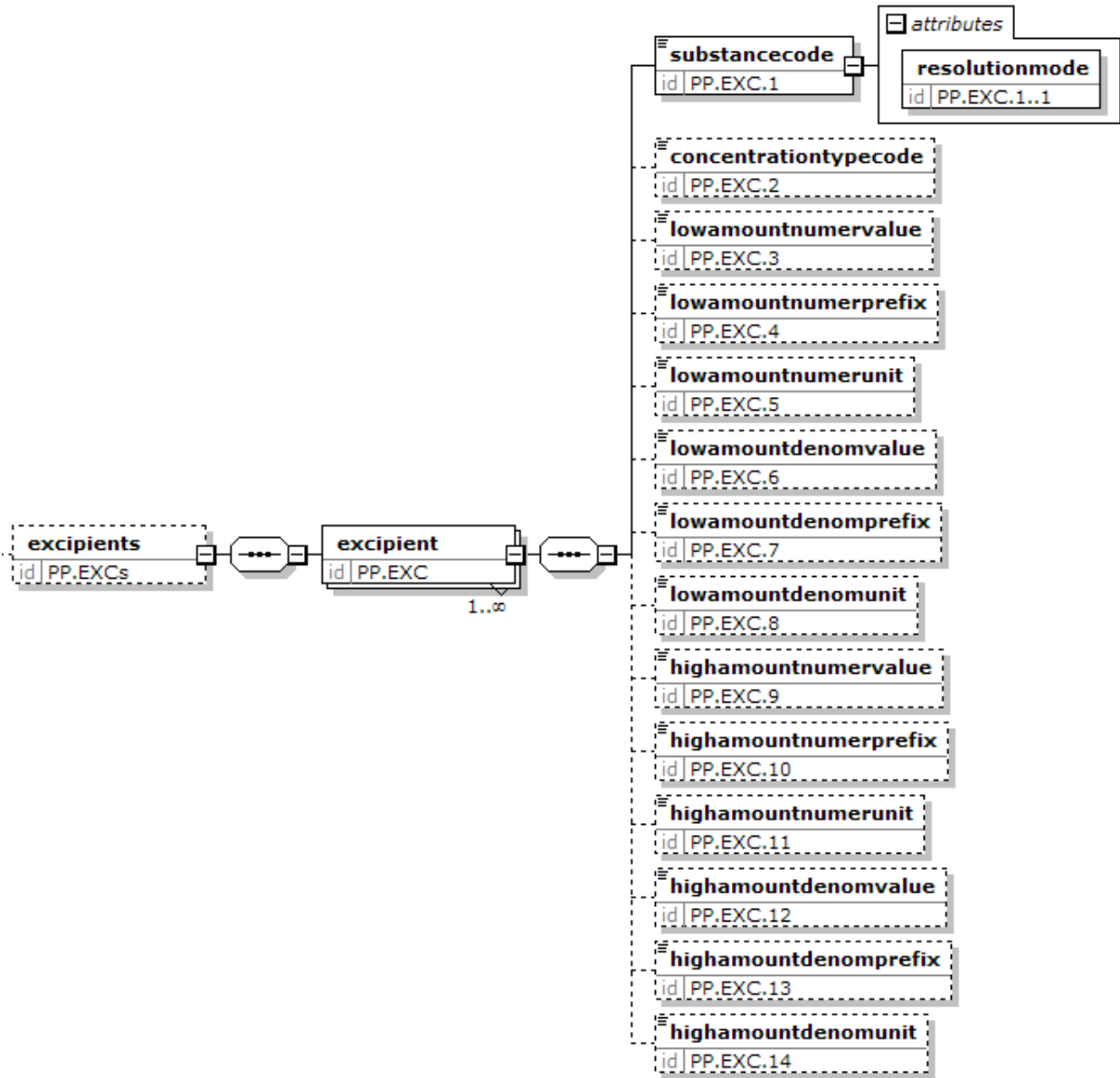
Each pharmaceutical product must contain information on:

- Active ingredient(s) - active ingredient substance name(s) and its/their concentration(s) can be found in section 2. Qualitative and Quantitative Composition of the corresponding SmPC;
- Excipient(s) - excipient substance name(s) can be found in section 6.1 List of excipients of the corresponding SmPC. It is optional to submit the concentration(s) of excipient(s);
- In some instances, pharmaceutical product can also contain adjuvants. Adjuvant substance name(s) and its/their concentration(s) can be found in section 2. Qualitative and Quantitative Composition of the corresponding SmPC.

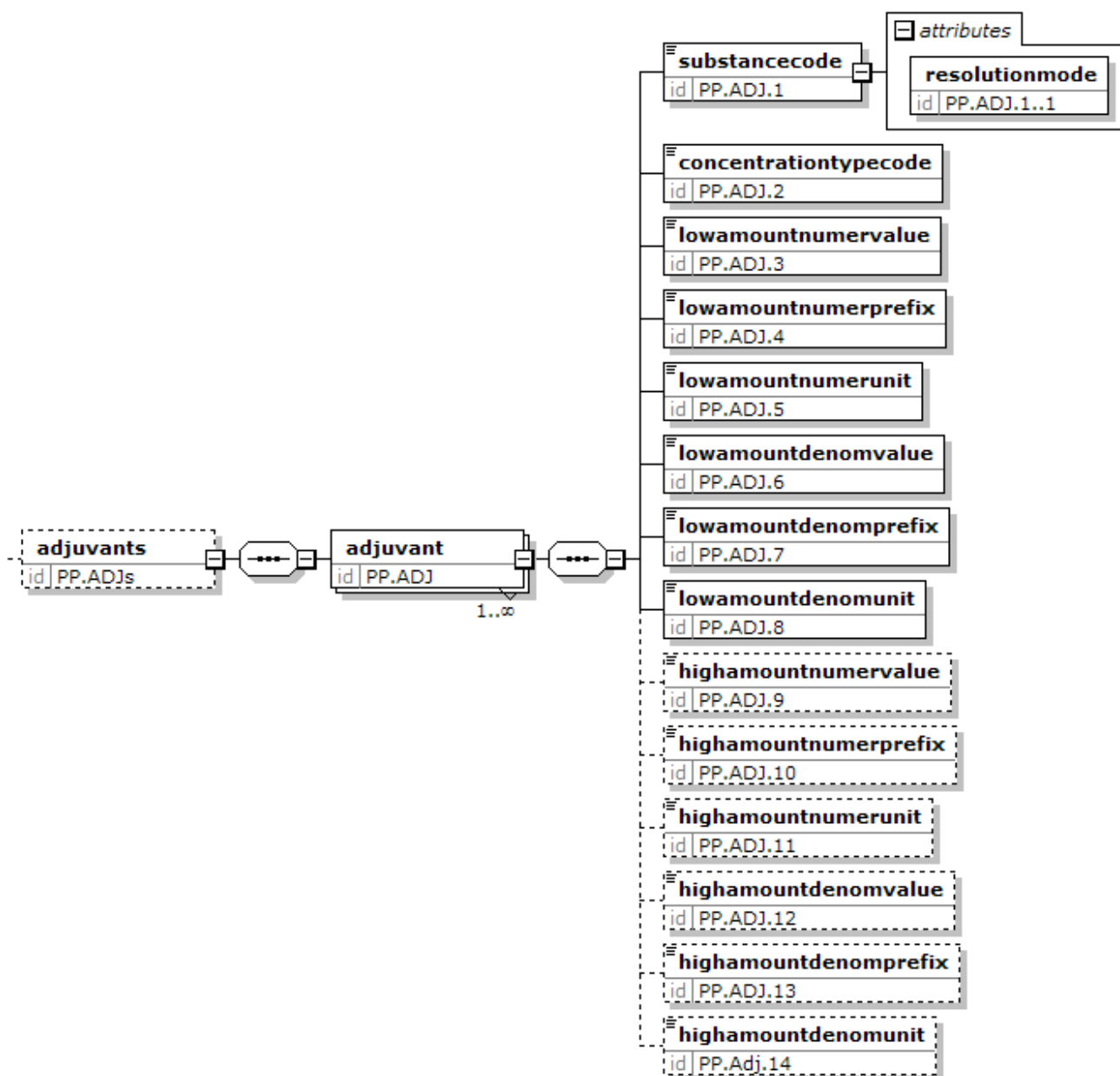
Pharmaceutical Product **active ingredient** element structure:



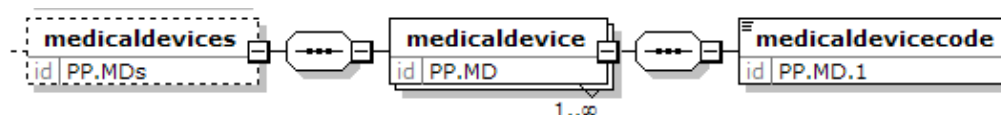
Pharmaceutical Product **excipient** element structure:



Pharmaceutical Product **adjuvant** element structure:



Pharmaceutical Product **medical device** element structure



NOTE 9

Only approved substances can be referenced in a pharmaceutical product within an authorised medicinal product entity.

Each approved substance successfully submitted in the XEVMPD has an assigned EV Code. The preferred name of the approved substance is entered in English. Each translation and synonym are linked to the master substance EV Code.

The substance name used in the pharmaceutical product must be in line with the substance name used in the SmPC and should provide the description of the substance within the medicinal product irrespective of national naming convention or any symbols, commas, and additional brackets, hyphens.

- If a substance name was previously successfully submitted in the XEVMPD and a substance EV Code has been assigned, the substance name can be selected from the available EudraVigilance look-up table (EVWEB users). Gateway users should populate the 'Active ingredient substance code' field (PP.ACT.1) with the assigned substance EV Code.

List of available approved substances with their assigned EV Codes can be found in the XEVMPD look-up table/Controlled Vocabulary (CV) lists published on the [Agency's website](#) - see "[eXtended Eudravigilance Product Dictionary \(XEVMPD\) substances](#)". The published XEVMPD substance controlled vocabulary list contains substances available at the time of publication.

The EudraVigilance look-up table contains the most up-to-date data as substance information is submitted to the XEVMPD on daily basis.

- If a new approved substance/substance translation or a synonym/alias needs to be submitted in the XEVMPD please follow the process described in the communication [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#) or in section [1.4. Initial submission of an approved substance](#) of this document.

EXAMPLE 42

Scenario 1 – Exact substance name is not available in the XEVMPD look-up table/published Controlled Vocabulary (CV) list but a similar substance name is listed

Section 6.1. List of excipients of an English SmPC states "IRON OXIDE BROWN (**E-172**)". The substance name as stated in the SmPC is not present in the XEVMPD look-up table/published Controlled Vocabulary (CV) list. However, an approved substance with a preferred name "IRON OXIDE BROWN (**E172**)" is available with EV Code SUB130375 and should therefore be referenced in the pharmaceutical product. A request for addition of "IRON OXIDE BROWN (E-172)" as a synonym to SUB130375 should be submitted to the Agency as a request logged with the EMA Service Desk portal (<https://servicedesk.ema.europa.eu/>). The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entry.

Section 2. Qualitative and Quantitative Composition of an English SmPC states "VORTIOXETINE **D,L**-LACTATE". The substance name as stated in the SmPC is not present in the XEVMPD look-up table/published Controlled Vocabulary (CV) list. However, an approved substance with a preferred name "VORTIOXETINE (**D,L**)-LACTATE" is available with EV Code SUB130400 and should therefore be referenced in the pharmaceutical product. A request for addition of "VORTIOXETINE D,L-LACTATE" as a synonym to SUB130400 should be submitted to the Agency as a request logged with the EMA Service Desk portal (<https://servicedesk.ema.europa.eu/>). The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entry.

Scenario 2 – Substance name is not available in the XEVMPD look-up table/published Controlled Vocabulary (CV) list

Section 6.1. List of excipients of a Czech SmPC states "Sepifilm 3011 oranžová", which is a translation of substance name "Sepifilm 3011 Orange". Neither the substance name as stated in the SmPC nor the preferred name in English is present in the XEVMPD look-up table/published Controlled Vocabulary (CV) list. A request for addition of a new preferred substance name and a translation should be submitted to the Agency as a request logged with the EMA Service Desk portal (<https://servicedesk.ema.europa.eu/>). The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entry.

Section 6.1. List of excipients of a French SmPC states "laque aluminique de rouge cochenille A (E124)", which is a translation of substance name "aluminium lake red cochenille A (E124)". Neither the substance name as stated in the SmPC nor the preferred name in English is present in the XEVMPD look-up table/published Controlled Vocabulary (CV) list. A request for addition of a new preferred substance name and a translation should be submitted to the Agency as a request logged with the EMA Service Desk portal (<https://servicedesk.ema.europa.eu/>). The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entry.

NOTE 10

If a pharmaceutical product contains no active ingredient, one of the excipients and its strength should be selected and entered as the active ingredient. The substance selected as the active ingredient should not be entered also as an excipient as this would result in receiving a negative XEVPRM acknowledgement due to duplication of the same substance within one pharmaceutical product.

When a substance contains multiple components, both the substance and the individual components should be submitted, providing that the substance has a descriptive level of information relevant to excipient in medicinal products (e.g. general terms not indicative of excipients in medicines are not accepted such as thickeners, ink, emulsifiers).

EXAMPLES:

- Thickeners (methylcellulose, xanthan gum);
- Stearate emulsifiers (polyethylene glycol sorbitan tristearate, macrogol stearate, glycerides);
- lemon flavour (maltodextrin, arabic gum, lactose, triethyl citrate).

In the authorised product entity, all of the substance names should be referenced separately since they are substance names referenced in an approved SmPC; i.e. methylcellulose, xanthan gum, stearate emulsifiers, polyethylene glycol, sorbitan tristearate, macrogol stearate, glycerides, lemon flavour, maltodextrin, arabic gum, lactose and triethyl citrate.

Further guidance on how to handle approved substance names is included in the '[EMA Substance names best practice](#)' document published in section "Data Quality-control methodology" on the [Agency's webpage](#).

1.2.17.4. Active ingredient substance code (PP.ACT.1)

The EV Code(s) of the substance(s) indicated as the active ingredient(s) of the medicinal product according to the description provided in section 2. Qualitative and Quantitative Composition of the corresponding SmPC must be specified.

The substance name must be specified in line with the description of the ingredients present in the medicinal product as described in the SmPC of the country of authorisation:

- substance(s) EV Code(s) must be provided
- For centrally authorised products (CAPs):
 - any missing translation names must be provided in all official languages based on the process described in section [1.4. Initial submission of an approved substance](#) of this document. See also [Table 1a- Authorised medicinal product – language requirements](#) for related information.
- For non-centrally authorised products (MRPs/DCPs/NAPs):
 - any missing translation names must be provided in all the applicable national languages based on the process described in section of this document. See also [Table 1a- Authorised medicinal product – language requirements](#) for related information.
- Any missing synonym/alias names that are in accordance with internationally recognised reference sources may be requested by means of the process described in section [1.4. Initial submission of an approved substance](#) of this document.

EXAMPLE 43

The SmPC of a medicinal product authorised in Germany states the following information:

2. QUALITATIVE UND QUANTITATIVE ZUSAMMENSETZUNG

1 g Creme enthält: 1,67 mg Gentamicinsulfat

The active substance (i.e. EV code of the active substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Gentamicinsulfat" (in German language). Since "Gentamicinsulfat" is already available in the XEVMPD look-up table/published Controlled Vocabulary (CV) list as a translation of SUB02327MIG with the preferred name "GENTAMICIN SULFATE", this EV Code should be referenced by the MAH in the product entity.

EXAMPLE 44

The SmPC of a medicinal product authorised in Italy states the following information:

2. COMPOSIZIONE QUALITATIVA E QUANTITATIVA

Una compressa rivestita contiene: Principio attivo - Paracetamolo 500 mg

The active substance (i.e. EV code of the active substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Paracetamolo" (in Italian language). Since "paracetamolo" is already available in the XEVMPD look-up table/published Controlled Vocabulary (CV) list as a translation of SUB09611MIG with the preferred name "paracetamol", this EV Code should be referenced by the MAH in the product entity.

EXAMPLE 45

The SmPC of a medicinal product authorised In Ireland states the following information:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg of metformin hydrochloride corresponding to 18 mg of metformin.

The active substance (i.e. EV Code of the active substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "metformin hydrochloride". Since "metformin hydrochloride" is already available as the preferred name of SUB03200MIG, this substance EV Code should be referenced by the MAH in the product entity.

EXAMPLE 46

The SmPC of a medicinal product authorised In Ireland states the following information:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Olanzapine hydrochloride corresponding to 0.2 mg Olanzapine.

Or

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 0.2 mg Olanzapine as Olanzapine hydrochloride.

Because the strength is available only for the moiety, the active substance (i.e. EV Code of the active substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Olanzapine". Since "Olanzapine" is already available as the preferred name of SUB09426MIG, this substance EV Code should be referenced by the MAH in the product entity.

EXAMPLE 47

The SmPC of a medicinal product authorised In Ireland states the following information:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of Levetiracetam (as hydrochloride).

Or

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each inl contains Levetiracetam hydrochloride corresponding to 10 mg/ml Levetiracetam after reconstitution.

The active substance (i.e. EV code of the active substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Levetiracetam". Since "Levetiracetam" is already available as the preferred name of SUB08459MIG, this substance EV Code should be referenced by the MAH in the product entity.

Table 3 - Requirements on how to reflect information on substance and strength in section 2. Qualitative and Quantitative Composition of the SmPC

Substance	Substance Strength	Reference Substance	Reference Substance Strength	Article 57(2) Requirements	Examples
✓	✓	✗	✗	Substance + Substance Strength	<p><i>Section 2 of SmPC states:</i> Each vial contains 1000 mg metformin, hydrochloride. After reconstitution, each ml of solution contains 100 mg metformin, hydrochloride.</p> <p><i>Article 57 requirement:</i> Substance: Metformin hydrochloride Strength: 100 mg/ml</p>
✓	✗	✓	✓	Reference Substance + Reference Substance Strength	<p><i>Section 2 of SmPC states:</i> Each capsule contains 250 mg olanzapine (as hydrochloride). Or Each capsule contains 250 mg olanzapine (as olanzapine hydrochloride).</p> <p><i>Article 57 requirement:</i> Substance: Olanzapine Strength: 250 mg/capsule</p>

Substance	Substance Strength	Reference Substance	Reference Substance Strength	Article 57(2) Requirements	Examples
x	x	✓	✓	Reference Substance + Reference Substance Strength	<p><i>Section 2 of SmPC states:</i></p> <p>One mL contains defibrotide 80mg corresponding to a quantity of 200 mg in 2.5 mL in a vial and equivalent to a concentration in the range of 4 mg/mL to 20 mg/mL after dilution.</p> <p><i>Article 57 requirement:</i></p> <p>Substance: Defibrotide Strength: 4 mg/ml - 20 mg/ml</p>
✓	✓	✓	✓	Substance + Substance Strength	<p><i>Section of SmPC states:</i></p> <p>Each tablet contains 12 mg loperamide hydrochloride corresponding to 10 mg loperamide.</p> <p><i>Article 57 requirement:</i></p> <p>Substance: Loperamide hydrochloride Strength: 12 mg/tablet</p>

1.2.17.5. Active ingredient substance strength

The strength of the substance name specified in the "Active ingredient substance code" (PP.ACT.1) must be specified in accordance with section 2. Qualitative and Quantitative Composition of the corresponding SmPC.

Whenever possible, the substance strength should be expressed as a unit of measurement.

Strength must be entered in the XEVMPD in accordance with the ISO IDMP standards based on a numerator and denominator. Strength can be therefore expressed in two ways:

- As a Unit of Measure

When the strength of a medicinal product described as a technical concept of a "Pharmaceutical Product" that has undergone a transformation (for example reconstitution) is to be specified, it is to be specified using the strength resulting from transformation undertaken exactly in accordance with the regulated product information (i.e. in the SmPC as per section 2. Qualitative and Quantitative Composition).

EXAMPLES of units of measure: 10 milligrams per 100 millilitres, 10 milligrams per 1 single day.

- As a unit a Presentation

The unit of presentation is a qualitative term describing the discrete unit in which a "pharmaceutical product" is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.

EXAMPLES of units of presentation: 250 milligrams per 1 single tablet, 10 millilitres per one single spoon.

Unit of presentation can be expressed as:

- *Strength*; e.g. spray/puff contains 100 mcg per actuation (unit of presentation = actuation);
- *Quantity*; e.g. bottle contains 100 ml per bottle (unit of presentation = bottle).

NOTE 11

Where an ingredient is present in the form of a salt or hydrate, the quantitative composition may be expressed in terms of the mass [or biological activity in International (or other) units where appropriate] of the active moiety (base, acid or anhydrous material).

The strength declared should be included in the SmPC. No calculations/conversions should be performed to obtain a figure.

- If the strength is declared as the amount of base then the base is the substance to be declared as the ingredient
- If the strength is declared as the amount of the salt then the salt is the substance to be declared as the ingredient
- In the rare examples where the strength of the salt and the base are both declared, then the salt is the substance to be declared as the ingredient. This is in line with IDMP where the both the substance (salt) and the reference substance (base/active moiety) will need to be defined.

EXAMPLE of Reference substance/strength:

"60 mg toremifene (as citrate)" or "toremifene citrate equivalent to 60 mg toremifene" – the substance 'toremifene' will be specified as the active ingredient in the pharmaceutical product.

NOTE 12

Where the active ingredient is an ester or pro-drug, the quantitative composition may be stated in terms of the quantity of that ester or pro-drug.

Further explanation on the expression of strength is provided in the [Notice to Applicants, Volume 2C - Regulatory Guidelines "Guideline on Summary of Product Characteristics – SmPC"](#).

1.2.17.6. Active ingredient concentration type Code (PP.ACT.2)

Concentration Type Code referencing the selected concentration type value must be specified.

The strength of the substance is to be specified as a quantity of the substance present in a medicinal product described as the technical concept of a "pharmaceutical product".

The following concentration type values (amount value types) are available for use as part of the XEVMPD look-up table/Controlled Vocabulary (CV) lists published on the [Agency's website](#) (see Extended EudraVigilance product report message concentration types):

- Equal (1);
- Range (2);
- Up to (3);
- Not less than (4);
- Approximately (5);
- Average (6).

EXAMPLE 48

The SmPC of a medicinal product authorised In Ireland states the following information:

2. Qualitative and Quantitative Composition

Each tablet contains 10 mg Diazepam

In accordance with the above information stated in the SmPC, the strength of the active ingredient should be expressed as per unit of presentation. The value should be set to "Equal (1)" and the strength will be expressed as 10 milligrams per 1 single tablet.

EXAMPLE 49

The SmPC of a medicinal product authorised In Ireland states the following information:

2. Qualitative and Quantitative Composition

Each vial contains 10 mg Paracetamol. After reconstitution, each ml of solution contains approximately 1 mg Paracetamol.

In accordance with the above information stated in the SmPC, the strength of the active ingredient should be expressed as per unit of measure. The value should be set to "Approximately (5)" and the strength will be expressed as 1 milligram per 1 millilitre.

EXAMPLE 50

The SmPC of a medicinal product authorised in Ireland states the following information:

2. Qualitative and Quantitative Composition

The concentrate for solution for infusion contains 1000 mg/ml Ibuprofen. After dilution, the concentration of Ibuprofen will be 100 mg/ml to 200 mg/ml depending on the age of the patient.

In accordance with the above information stated in the SmPC, the strength of the active ingredient should be expressed as per unit of measure. The value should be set to "Range (2)" and the strength will be expressed as 100 milligram per 1 millilitre to 200 milligram per 1 millilitre.

1.2.17.7. Active ingredient substance value(s)

A numerator value and numerator unit as well as a denominator value and denominator unit must be specified in accordance with section 2. Qualitative and Quantitative Composition of the corresponding SmPC.

(Low Amount) Numerator Value (PP.ACT.3)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator value of the strength of the active substance.

100 mg/ml: "lowamountnumervalue" = 100

(Low Amount) Numerator Prefix (PP.ACT.4)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator unit prefix value of the strength of the active substance.

100 mg/ml: "lowamountnumerprefix" = Milli (1×10^{-3})

(Low Amount) Numerator Unit (PP.ACT.5)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator unit value of the strength of the active substance.

100 mg/ml: "lowamountnumerunit" = Gram(s)

(Low Amount) Denominator Value (PP.ACT.6)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator value of the strength of the active substance.

100 mg/ml: "lowamountdenomvalue" = 1

(Low Amount) Denominator Prefix (PP.ACT.7)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator unit prefix value of the strength of the active substance.

100 mg/ml: "lowamountdenomprefix" = Milli (1×10^{-3})

(Low Amount) Denominator Unit (PP.ACT.8)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator unit value of the strength of the active substance.

100 mg/ml: "lowamountdenomunit" = Litre

High Amount Numerator Value (PP.ACT.9)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator value of the strength of the active substance.

High Amount Numerator Prefix (PP.ACT.10)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator unit prefix value of the strength of the active substance.

High Amount Numerator Unit (PP.ACT.11)

refers to the strength of the active substance expressed in a ratio scale. It refers to the numerator unit value of the strength of the active substance.

High Amount Denominator Value (PP.ACT.12)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator value of the strength of the active substance.

High Amount Denominator Prefix (PP.ACT.13)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator unit prefix value of the strength of the active substance.

High Amount Denominator Unit (PP.ACT.14)

refers to the strength of the active substance expressed in a ratio scale. It refers to the denominator unit value of the strength of the active substance.

EXAMPLE 51

Administered dose = 200 mg per capsule

Numerator value: 200

Numerator prefix: milli

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: single

Denominator unit (of presentation): capsule

EXAMPLE 52

Administered dose = 200 microgram/puff

Numerator value: 200

Numerator prefix: micro

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: single

Denominator unit (of presentation): puff

EXAMPLE 53

Administered dose = 0.5 – 2 mg/ml

Low amount numerator value: 0.5

Low amount numerator prefix: milli

Low amount numerator unit: gram(s)

Low amount denominator value: 1

Low amount denominator prefix: milli

Low amount denominator unit (of measurement): litre(s)

High amount numerator value: 2

High amount numerator prefix: milli

High amount numerator unit: gram(s)

High amount denominator value: 1

High amount denominator prefix: milli

High amount denominator unit (of measurement): litre(s)

EXAMPLE 54

Administered dose = 5 mg/1 measuring spoon (if the spoon is provided as part of the package or not does not have any impact on making reference to the unit of presentation)

Numerator value: 5

Numerator prefix: milli

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: single

Denominator unit (of presentation): spoon

EXAMPLE 55

1 dose (1 ml) contains Hepatitis A surface antigen 10 micrograms

Numerator value: 10

Numerator prefix: micro

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: milli

Denominator unit (of measurement): litre(s)

EXAMPLE 56

1 dose contains Hepatitis B surface antigen 20 micrograms

Numerator value: 20

Numerator prefix: micro

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: single

Denominator unit (of presentation): dose

EXAMPLE 57

1 ml contains Hepatitis C surface antigen 30 micrograms

Numerator: 30

Numerator prefix: micro

Numerator unit: gram(s)

Denominator value: 1

Denominator prefix: milli

Denominator unit (of measurement): litre(s)

1.2.17.8. Excipient substance code (PP.EXC.1)

The EV Code(s) of the substance(s) indicated as excipient(s) of the medicinal product according to the description provided in section 6.1. List of excipients of the corresponding SmPC must be specified.

The substance name must be specified in line with the description of the ingredients present in the medicinal product as described in the SmPC of the country of authorisation:

- substance(s) EV Code(s) must be provided
- For centrally authorised products (CAPs):
 - any missing translation names must be provided in all official languages based on the process described in section [1.4. Initial submission of an approved substance](#) of this document. See also [Table 1a- Authorised medicinal product – language requirements](#) for related information.
- For non-centrally authorised products (MRPs/DCPs/NAPs):
 - any missing translation names must be provided in all the applicable national languages based on the process described in section [1.4. Initial submission of an approved substance](#) of this document. See also [Table 1a- Authorised medicinal product – language requirements](#) for related information.
- Any missing synonym/alias names that are in accordance with internationally recognised reference sources may be requested by means of the process described in section [1.4. Initial submission of an approved substance](#) of this document.

See also [NOTE 9](#) for related information.

EXAMPLE 58

The SmPC of a medicinal product authorised in Germany states the following information:

6.1 Liste der sonstigen Bestandteile

Wasser für Injektionszwecke

The excipient substance (i.e. EV code of the excipient substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Wasser für Injektionszwecke" (in German language). Since "Wasser für Injektionszwecke" is already available as a translation of SUB12398MIG, this substance EV Code should be referenced by the MAH in the product entity.

EXAMPLE 59

The SmPC of a medicinal product authorised in the Czech Republic states the following information:

6.1 Seznam pomocných látek

Granulovaná mikrokrytalická celuloza

Magnesium-stearát

The excipient substances (i.e. EV code of the excipient substances in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "Granulovaná mikrokrytalická celuloza" and "Magnesium-stearát" (both in Czech language). Since "Granulovaná mikrokrytalická celuloza" is already available as a translation of SUB122000, this substance EV Code should be referenced by the MAH in the product entity.

Since "Magnesium-stearát" is already available as a translation of SUB12527MIG, this substance EV Code should be referenced by the MAH in the product entity.

1.2.17.9. Excipient substance strength

It is optional to describe the strength(s) of excipient(s). If this information is provided, the strength(s) of the excipient(s) as listed in section 6.1 List of excipients of the corresponding SmPC must be specified in the pharmaceutical product.

The same principles as described in sections [1.2.17.6. Active ingredient concentration type Code \(PP.ACT.2\)](#) and [1.2.17.7. Active ingredient substance value\(s\)](#) of this document apply to the description of strength of excipients should the MAH wish to submit it.

1.2.17.10. Adjuvant substance code (PP.ADJ.1)

The EV Code(s) of the substance(s) indicated as adjuvant(s) of the medicinal product according to the description provided in section 2. Qualitative and Quantitative Composition (or section 6. List of excipients) of the corresponding SmPC must be specified.

The substance name must be specified in line with the description of the ingredients present in the medicinal product as described in the SmPC of the country of authorisation:

- substance(s) EV Code(s) must be provided
- For centrally authorised products (CAPs):
 - any missing translation names must be provided in all official languages based on the process described in section [1.4. Initial submission of an approved substance](#) of this document. See also [Table 1a- Authorised medicinal product – language](#) requirements for related information.
- For non-centrally authorised products (MRPs/DCPs/NAPs):

- any missing translation names must be provided in all the applicable national languages based on the process described in section [1.4. Initial submission of an approved substance](#) of this document. See also [Table 1a- Authorised medicinal product – language](#) requirements for related information.
- Any missing synonym/alias names that are in accordance with internationally recognised reference sources may be requested by means of the process described in section [1.4. Initial submission of an approved substance](#) of this document.

See also [NOTE 9](#) for related information.

1.2.17.11. Adjuvant substance strength

The strength of the substance stated as the adjuvant of the pharmaceutical product in section 2. Qualitative and Quantitative Composition of the corresponding SmPC must be specified.

Whenever possible, the substance strength should be expressed as a unit of measurement.

The same principles as described in sections [1.2.17.6. Active ingredient concentration type Code \(PP.ACT.2\)](#) and [1.2.17.7. Active ingredient substance value\(s\)](#) of this document apply to the description of strength of adjuvants.

EXAMPLE 60

The SmPC of a medicinal product authorised In Ireland states the following information:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hepatitis B surface antigen*.....20 micrograms/ml

*adjuvanted on aluminium hydroxide (0.2 micrograms/ml Al³⁺)

The adjuvant (i.e. EV code of the adjuvant substance in the local language) to be referenced in the pharmaceutical product section of the AMP entity in the XEVMPD must be "aluminium hydroxide" (i.e. EV Code SUB33625) and the strength is "0.2 micrograms/ml".

1.2.17.12. Medical device Code (PP.MD.1)

The EV code of a medical device where it forms an integral part of the medicinal product must be specified.

Medical device description is currently only required for Advanced Therapy Medicinal Products (ATMPs), where applicable (see Regulation (EC) No 1394/2007).

EXAMPLE - medical device: [COLLAGEN SCAFFOLD](#)

Where a medical device term is required for an ATMP, the marketing authorisation holder needs to submit a request for a term assignment in the EMA Service Desk portal (<https://servicedesk.ema.europa.eu>) and the Agency will provide a code and term for the medical device to the marketing authorisation holder.

List of available medical devices with their assigned EV Codes can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the [Agency's website](#) - see "eXtended Eudravigilance Product Dictionary (XEVMPD) medical devices".

1.2.18. Product ATC Code(s) (AP.ATC.1)

The ATC code as described in Section 5.1 Pharmacodynamic properties of the SmPC must be specified.

A "standard" ATC code must be specified whenever possible.

- MAHs may reference deprecated ATC Codes in Authorised Medicinal Products to facilitate the Article 57(2) electronic submission of information on medicines.
- All five levels of the ATC code can be used.
- Where, for certain types of medicinal products (e.g. authorised or registered herbal medicinal products), an ATC Code is usually not allocated the ATC Code value **NOTAPPLIC** may be specified.
- Where an ATC Code has been requested by the marketing authorisation holder but has not yet been assigned by the WHO Collaborating Centre for Drug Statistics Methodology, the proposed ATC Code value must be specified even if the SmPC states "not yet assigned".
- Where an ATC Code has not been requested by the marketing authorisation holder and the SmPC states "not yet assigned", the ATC Code value **NOTASSIGN** must be specified.
- In case that multiple ATC Codes are applicable for one authorised medicinal product, multiple ATC Codes can be referenced within one AMP entity.

For EVWEB users, the list of ATC Codes is available in the corresponding XEVMPD look-up table in the XEVMPD.

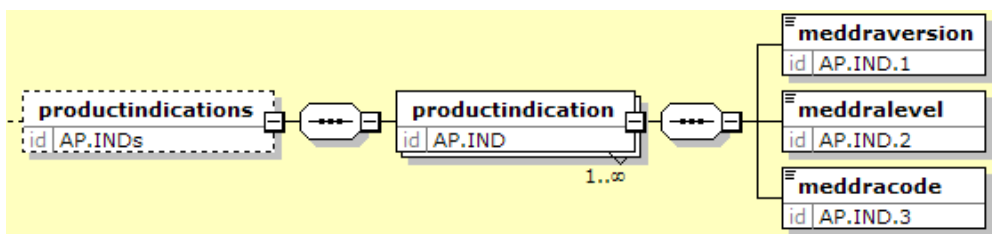
Gateway users can obtain the list of ATC Codes from the [WHO Collaborating Centre for Drug Statistics Methodology](#).

If the ATC Code for a medicinal product is not part of the ATC Index published by the WHO, the ATC Code should be provided as a "proposed term" in the XEVPRM.

See section [1.7. Initial submission of an ATC Code](#) of this document for further information on how to submit a proposed ATC Code in the XEVMPD.

1.2.19. AMP - Product indications (AP.INDs)

Description of the authorised indication(s) as reflected in Section 4.1 Therapeutic Indications of the SmPC must be provided in this section.



A copy of MedDRA needs to be obtained from [MedDRA](#).

Further guidance on coding of indications based on section 4.1 of the Summary of Product Characteristics (SmPC) using MedDRA terminology is available in the document [Coding of indications in the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\)](#).

1.2.19.1. MedDRA version (AP.IND.1)

The indication(s) is/are to be coded using MedDRA in its latest version where applicable.

Each indication is to be coded using MedDRA in its latest current version for the operation types "Insert (1)" and "Update (2)" in the context of the data submission maintenance (e.g. variation, renewal, etc.). The next official MedDRA version can also be used if a term of that version is required.

EVWEB users may specify one of the following MedDRA versions for the operation types "Invalidate MA (6)", "Nullification (4)" and "Update (2)" (not in the context of data submission maintenance):

- the latest current version of MedDRA;
- the two previous version of MedDRA;
- the next MedDRA version (for supplemental terms).

EV-POST and Gateway users may specify any MedDRA version after version 7.1 (inclusive) for the operation types "Invalidate MA (6)", "Nullification (4)" and "Update (2)" (not in the context of data submission maintenance).

Note that new MedDRA versions are implemented in XEVMPD towards the end of the **transition period defined by MSSO**. Therefore the concept of "latest current version of MedDRA" refers to the system availability and not to the publishing of a more recent version.

For instance, MedDRA 17.0 was considered the latest current version up to November 2014. Whilst MedDRA 17.1 was published in September 2014, MedDRA 17.1 became current as of November 2014.

1.2.19.2. MedDRA level (AP.IND.2)

Low Level Terms (LLT) must be specified.

1.2.19.3. MedDRA Code (AP.IND.3)

The indication(s) is/are to be coded using the English term and corresponding code. Where a specific language is not supported in MedDRA, the MedDRA Code associated with the English equivalent term should be used.

If a term of the next official MedDRA version is required, it can be entered as supplemental MedDRA term.

Multiple terms can be used to code the medical concepts of indication(s), the signs, symptoms or intended effects. The use of qualifiers (e.g. comorbidities, population specifics) will be possible with the implementation of the ISO IDMP standards.

It is not necessary to update medicinal product entries when a new MedDRA version is released. In the context of the data submission maintenance (e.g. if there is a need of notification of a variation with an 'Update (2)' operation type), if a new MedDRA version is available, the latest current version should be used to codify the indications.

As a general principle, when updating the product information, terms deprecated (non-current) in a new version of MedDRA cannot be referenced in any XEVPRM submitted thereafter and current terms are to be provided instead.

For coding instructions, please refer to MedDRA Term Selection: Points to Consider Document available on [MedDRA website](#). Summary of Changes to MedDRA Term Selection are also available on [MedDRA website](#).

Efforts should be made to capture the most granular and comprehensive level of information available in MedDRA; where the stage or type of a disease is available, this should be captured as well.

EXAMPLE 61

Scenario 1

Section 4.1 Therapeutic Indications of the SmPC states "Treatment of COPD"

Term coded in MedDRA: COPD (LLT=10010952)

Scenario 2

Section 4.1 Therapeutic Indications of the SmPC states "Treatment of Chronic obstructive pulmonary disease"

Term coded in MedDRA: Chronic obstructive pulmonary disease (LLT=10009033)

Scenario 3

Section 4.1 Therapeutic Indications of the SmPC states "Treatment of Chronic obstructive pulmonary disease (COPD)"

Term coded in MedDRA: Chronic obstructive pulmonary disease (LLT=10009033)

Term coded in MedDRA: COPD (LLT=10010952)

EXAMPLE 62

Section 4.1 Therapeutic Indications of the SmPC states "Treatment of motor fluctuations in patients with Parkinson's disease"

Term coded in MedDRA: Motor fluctuations (LLT=10067208)

EXAMPLE 63

Section 4.1 Therapeutic Indications of the SmPC states "None. The product is intended as a diluent for Carwash Powder for Injection"

Term coded in MedDRA: Medication dilution (LLT=10063482)

EXAMPLE 64

Section 4.1 Therapeutic Indications of an Italian SmPC states:

"ricidiva di candidiasi orofaringea o esofagea in pazienti con infezione da HIV che sono ad alto rischio di subire ricadute"

Term coded in MedDRA:

Oropharyngeal candidiasis recurrent (LLT=10066493)

Oesophageal candidiasis recurrent (LLT=10066491)

Additional MedDRA coding examples

1/

"Drug is indicated in the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture"

Term coded in MedDRA:

Osteoporosis (LLT= 10031282)

Osteoporosis steroid-induced (LLT=10031287)

Osteoporosis postmenopausal (LLT=10031285)

2/

"Indicated for treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas"

Term coded in MedDRA:

Pancreatic adenocarcinoma (LLT=10051971)

Pancreatic adenocarcinoma metastatic (LLT=10033599)

Where two or more similar MedDRA terms exist, it is preferable to capture only one of them (e.g.: either "Pancreatic adenocarcinoma (LLT=10051971)" or "Adenocarcinoma pancreas (LLT=10052747)" is acceptable).

3/

EXAMPLE 64.3

"Drug is indicated for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis."

Term coded in MedDRA:

Ankylosing spondylitis (LLT= 10002556)

Osteoarthritis (LLT= 10031161)

Rheumatoid arthritis (LLT= 10039073)

4/

"Drug is indicated for the treatment of patients with locally advanced or metastatic epithelial ovarian carcinoma, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy."

Term coded in MedDRA:

Ovarian epithelial cancer (LLT=10061328)

Ovarian epithelial cancer metastatic (LLT=10033158)

The information related to co-medication and other qualifiers for treatment, target population or health status or population will not be captured at this stage.

The information related to the status of the disease is to be captured, as available in the current MedDRA version.

5/

"Drug is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy".

Term coded in MedDRA:

Breast Cancer (10006187)

Breast cancer recurrent (10006198)

Breast cancer metastatic (10055113)

1.2.20. Previous EV Code (AP.PEV.1)

The EV Code of the development product may be specified if the authorised product was submitted to the XEVMPD in its development form.

The EV Code of an authorised product must be specified in the context of Transfer/Renewal of Marketing Authorisation as applicable.

- If the authorised product was submitted to the XEVMPD in its development form (as a development medicinal product), this field may contain the EV Code assigned to the development medicinal product (DMP).

The referenced **EV Code** must match a **development product EV Code** in the XEVMPD. Failure to comply leads to the generation of a 02 negative acknowledgement and the individual product is rejected.

- If an authorised medicinal product submitted in the XEVMPD was subject to a marketing authorisation transfer between organisations registered in EV under separate headquarters, the new authorised medicinal product entity must reference the EV Code of the previous AMP entity as applicable. The referenced **EV Code** must match at least one **authorised product EV Code** in the XEVMPD. The EV Code of the AMP must not be a nullified EV Code. Failure to comply leads to the generation of a 02 negative acknowledgement and the individual product is rejected.
- If an authorised medicinal product submitted in the XEVMPD was subject to a marketing authorisation transfer within the same organisation (i.e. organisations under the same EV headquarter), and the MAH used the simplified process to notify the Agency of this transfer, the updated authorised medicinal product entity must reference the EV Code of the AMP entity that is being updated as applicable.

See section [2.4.3. Transfer of marketing authorisation](#) of this document for further information on transfer of marketing authorisation.

- If an authorised medicinal product submitted in the XEVMPD was a subject to a marketing authorisation renewal where a new marketing authorisation number has been assigned by the competent authority, the new authorised medicinal product entity must reference the EV Code of the previous AMP entity as applicable. The referenced **EV Code** must match at least one **authorised product EV Code** in the XEVMPD. The EV Code of the AMP must not be a nullified EV Code. Failure to comply leads to the generation of a 02 negative acknowledgement and the individual product is rejected.

1.2.21. AMP - Printed product information (PPI) attachments

A copy of the SmPC as authorised by the Authorising Body must be provided as a PPI attachment to the authorised medicinal product entity.

Where, in exceptional circumstances, the SmPC is not available as part of the marketing authorisation, an equivalent document that facilitates the data quality assurance process by the Agency (e.g. English common text, PIL or other similar text as authorised by the Authorising Body) should be provided.

In case where the approved SmPC does not state an authorisation number, a date of authorisation/renewal or the MAH, a copy of the document granting or renewing marketing authorisation should also be provided as an additional PPI attachment.

See section [1.10. Submission of an attachment](#) for further information.

1.2.21.1. Attachment EV Code (AP.PPI.1)

The EV Code of the attachment referring to the authorised medicinal product must be specified.

- If the attachment to be referenced in the AMP entity was already submitted in the XEVMPD and an attachment EV Code has been assigned, the attachment can be selected from the available EudraVigilance look-up table (EVWEB users). Gateway users should populate the 'Attachment EV Code' field (AP.PPI.1) with the assigned attachment EV Code received in the XEVPRM Acknowledgement.

The pattern of the EV Code is 'ATT' followed by a number.

- If the corresponding attachment is not available in the XEVMPD, the attachment can be added using the attachment section of the XEVPRM.

See section [1.10. Submission of an attachment](#) of this document for further information on how to submit a PPI attachment in the XEVMPD.

NOTE 13

It is not possible to submit only a PPI attachment entity in an XEVPRM in EVWEB. At least one of the submitted authorised medicinal products that will refer to the new attachment (SmPC) should also be present in the same XEVPRM.

1.2.21.2. Attachment validity declaration (AP.PPI.2)

Validity confirmation that the referenced attachment is the latest version of the documentation must be provided when performing an update or insert of an authorised product where a referenced PPI attachment was previously loaded in the XEVMPD.

The value 'Valid (1)' specifies that the attachment is the latest version.

When all of the above fields required for the submission of an AMP are specified as applicable in the XEVPRM, and following a successful submission of the XEVPRM in the XEVMPD, a local code will be assigned as an internal reference code until an EV Code has been provided as part of the acknowledgement process.

Following a successful insert, an EV Code for the authorised medicinal product entity will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for a medicinal product is 'PRD' followed by a number.

1.3. Initial submission of a QPPV information

EU QPPV, and where such does not exist, the local QPPV (e.g. for purely national authorisations) must register with EudraVigilance.

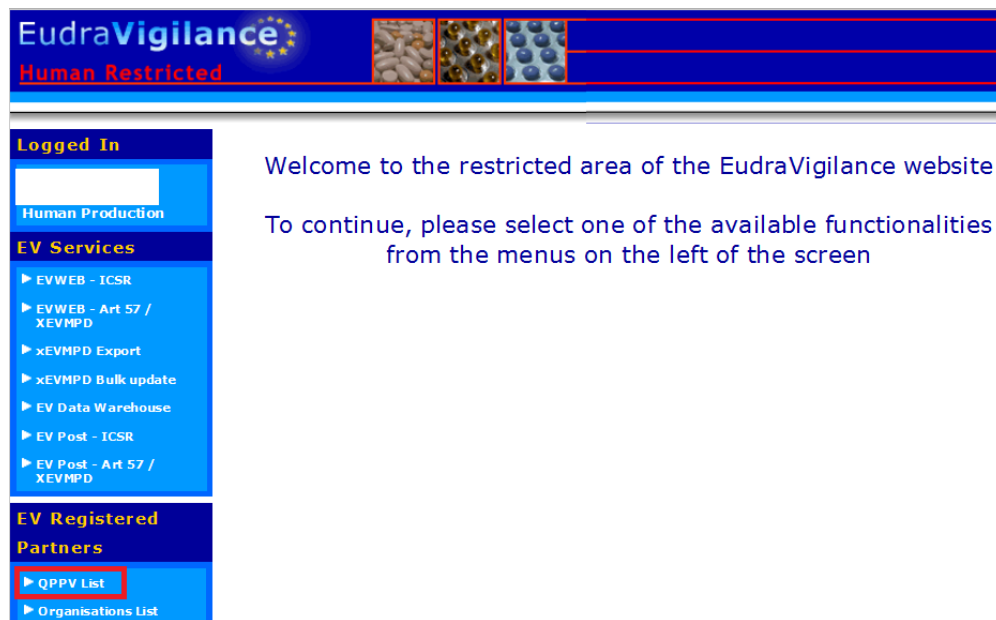
MAHs are legally required to have a qualified person for pharmacovigilance (QPPV) based in the European Union (EU) in place at all times, in line with [Directive 2001/83/EC](#) Article 104(3)(a).

Detailed information on how to register a QPPV can be obtained on the [EudraVigilance registration webpage](#) or in the [EMA EudraVigilance Registration Manual](#).

From 26 July 2018, QPPVs are required to self-register in the [EMA Account Management Platform](#). Following the self-registration of the QPPV in the EMA Account Management Platform the QPPV submits an [EMA Service Desk portal](#) request requesting his/her role to be certified by the EMA. Once the role is approved by the EMA, the QPPV retrieves the QPPV Code assigned.

The QPPV code can be retrieved by the QPPV and/or MAH users registered under the organisation's HQ from:

- The EudraVigilance website (restricted area accessible for registered users only) under "QPPV list" (by Gateway/EVWEB users); i.e.:



- or in the look-up table of the "QPPV" field in the XEVMPD Data Entry Tool (EVWEB) (by EVWEB users).

Any changes of the QPPV details (e.g. change of telephone number/address or surname of the QPPV) must be updated in the user's profile via the [EMA Account Management Platform](#) by the user. The changes must be made immediately and no later than 30 calendar days from the date the changes apply.

1.4. Initial submission of an approved substance

New approved substance information is submitted in the XEVMPD in an XEVPRM with the operation type 'Insert (1)' by the EMA.

The preferred name and alias(es) must be in English.

Substance/alias translation(s) must be provided in all official EU language(s) for CAPs and all national language(s) of the country/countries of authorisation for NAPs/MRPs/DCPs by the MAHs.

Each approved substance successfully submitted in the XEVMPD has an assigned EV Code. The preferred name of the substance is entered in English.

- The name(s) of the substance in individual national languages is/are listed as "Translations".
- The Agency supports non-Latin /accented character set EEA languages. The UTF-8 character set should be used.
- For WEB Trader users, the submission in non-Latin characters should be done using the XHTML version of XEVMPD Data Entry Tool (EVWEB) (this option should be selected in the display setting drop down menu in the top left corner of EVWEB). The only exception is the tree view in XEVMPD Data Entry Tool (EVWEB), which will not show the non-Latin characters.
- Any synonym(s)/alias(es) of the substance is/are listed as "Synonyms"/"Alias(es)".

As communicated in the [Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\): Submission of substance information](#) document, in the context of improvement of the XEVMPD Substance Controlled Vocabulary data quality, the XEVMPD business rules were revised to reject any operation type related to submission of **approved substances**.

This implies that any XEVPRM messages containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of an approved substance will be rejected and will generate a negative XEVPRM acknowledgement.

Providing that an approved substance is not listed in the [XEVMPD substance controlled vocabulary list](#) (sheets **1_Substance CV** and **4b_ Invalid substance names**) available in the 'Controlled Vocabularies' section of the [Data submission on authorised medicines - Guidance documents webpage](#), or in the XEVMPD substance look-up table, MAHs should submit their substance requests or any substance related enquiries via the EMA Service Desk (<https://servicedesk.ema.europa.eu/>).

Guidance on how to handle approved substance names is included in the '[EMA Substance names best practice](#)' document published in section "Data Quality-control methodology" on the [Agency's website](#).

Any requests containing 5 substances and more (insert and/or update) should be submitted in an Excel spreadsheet, which will then be sent back to the requestor with the assigned EV codes and/or comments where applicable.

Should the Summary of Product Characteristics (SmPC) or Patient Information Leaflet (PIL) be used as the reference source, the SmPC/PIL should be attached to the request. An EV Code of an authorised medicinal product referencing an SmPC or PIL where the requested substance name is included can be provided instead of the actual SmPC/PIL attachment within the request.

To request a new approved substance to be inserted in the XEVMPD:

- Log a request with the EMA Service Desk (<https://servicedesk.ema.europa.eu/>);

- *'Request for an insert of a new approved substance'* should be stated in the subject of the request;
- The substance name in English, substance class and reference source need to be included in the request.

Please see the [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) substance classes](#) Controlled Vocabulary published on the [Agency's website](#) for further information on available substance class values.

Please see the [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) reference sources](#) Controlled Vocabulary published on the [Agency's website](#) for further information on available reference source values.

- If requesting that a translation is added to an approved substance entity, the translation and the applicable language information should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
- If requesting that an alias is added to the substance entity, the alias and reference source should be included in the request.

The Agency will process the request in the XEVMPD and provide the MAH with the master substance EV Code to be referenced in their product entity as part of the electronic submission of medicinal product information under Article 57(2) provision.

To request an update of an existing approved substance in the XEVMPD to add a substance translation or an alias:

- Log a request with the EMA Service Desk (<https://servicedesk.ema.europa.eu/>);
- *'Request for an update of an approved substance'* should be stated in the request subject;
 - The translation and the applicable language information should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
 - If requesting that an alias should be added to the substance entity, the alias and reference source should be included in the request.

The Agency will process the requests in the XEVMPD.

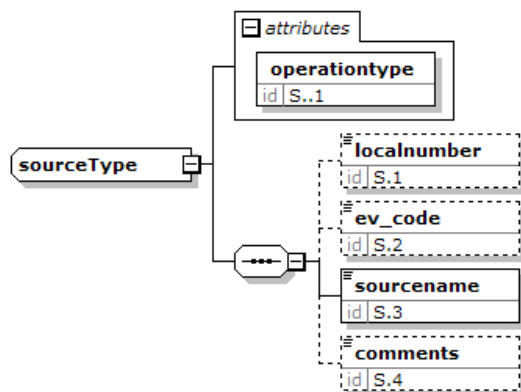
MAHs should use the master EV Code of the approved substance with the preferred name in English in their product entries as part of the electronic submission of medicinal product information under Article 57(2) provision.

1.5. Initial submission of a reference source

New reference source information must be submitted in the XEVMPD in an XEVPRM with the operation type 'Insert (1)'

- List of available reference sources with their assigned EV Codes can be found in the EudraVigilance look-up table and in the Controlled Vocabulary lists published on the [Agency's website](#) - see [eXtended Eudravigilance Product Dictionary \(XEVMPD\) reference sources](#).

Reference source elements structure:



1.5.1. Local Number (S.1)

Local number is a unique reference number that must be assigned for a reference source entity in the XEVPRM following an operation type 'Insert' (1).

When a new reference source is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to the reference source. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to retrieve the corresponding EV Code.

EXAMPLE: XEVPRM – Insert of a new reference source

```
<sources>
- <source operationtype="1">
  <localnumber>3</localnumber>
  <sourcename>Example Source</sourcename>
</source>
</sources>
</evprm>
```

EXAMPLE: XEVPRM Acknowledgement – Insert of a new reference source

```

- <reportacknowledgment>
  <reportname>SOURCE</reportname>
  <localnumber>3</localnumber>
  <ev_code>SRC12345</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>

```

1.5.2. EV Code (S.2)

EudraVigilance (EV) Code of the reference source must be specified if the operation type is NOT an 'Insert'.

I.e. if maintenance related operations are performed on a reference source entity successfully inserted in the XEVMPD, the EV Code of the reference source entity must be referenced in this field).

1.5.3. Reference source name (S.3)

The reference source name must be provided as mandatory information.

1.5.4. Comment (S.4)

Further information on the reference source may be provided in the comment field, if required.

When operation type 'Nullification' (4) is performed on a reference source entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

When all of the above fields required for the submission of a reference source are specified as applicable, and following a successful insert in the XEVMPD, an EV Code for the reference source will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for a reference source is 'SRC' followed by a number.

1.6. Initial submission of a marketing authorisation holder (MAH) organisation

New organisation information must be submitted in the XEVMPD in an XEVPRM with the operation type 'Insert (1)'.

The organisation information (i.e. MAH name and MAH address) refer to the legal entity of the medicinal product in a given country as indicated in section 7. Marketing Authorisation Holder of the SmPC.

List of available MAH organisations with their assigned EV Codes can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the [Agency's website](#) - see [EudraVigilance eXtended Medicinal Product Dictionary \(XEVMPD\) organisations](#).

NOTE 14

- The MAH name must be submitted providing the name of the legal entity in a given country regardless of any naming conventions/differences in trade style/characters specified in section 7. Marketing Authorisation Holder of various SmPCs. The same MAH/Legal entity in a given country for the applicable AMPs must be referenced as appropriate.
- The name and address of the Organisation should be provided consistently and providing the most complete information e. g. "Avenue" instead of "Av"., "Road" instead of "Rd" etc.
- The company's legal status does not need to be written in full (e.g. "Ltd." doesn't need to be changed to "Limited", "S.p.A." doesn't need to be changed to "Società Per Azioni", GmbH doesn't need to be changed to "Gesellschaft mit beschränkter Haftung".)

EXAMPLE 65

Scenario 1

Section 7. Marketing Authorisation Holder of the SmPC states "Pharma XYZ **Ltd** at the location "X".

- The organisation name as stated in the SmPC is not present in the XEVMPD look-up table/available Controlled Vocabulary (CV) list "eXtended Eudravigilance Product Dictionary (XEVMPD) organisations".
- Organisation "Pharma XYZ **Limited**" at the location "X" is available in the XEVMPD look-up table/available Controlled Vocabulary (CV) list "eXtended Eudravigilance Product Dictionary (XEVMPD) organisations" with the assigned EV Code "ORG1234". It is the same legal entity.

Since organisation entity "ORG1234" already contains the organisation details as the details stated in section 7. of the SmPC, it should be referenced in the pharmaceutical product.

It is not necessary to create a new MAH organisation entity with the name "Pharma XYZ **Ltd**" at the location "X" because "Pharma XYZ **Limited**" already exists in the XEVMPD and an EV Code has been assigned.

All AMPs for which "Pharma XYZ **Ltd**" at the location "X" is the MAH as per the corresponding SmPC should reference "Pharma XYZ **Limited**" (ORG1234) – the name of the organisation may be updated from "Pharma XYZ Limited" to "Pharma XYZ Ltd." should the owner organisation that submitted this entity wish to do so.

Scenario 2

Section 7. Marketing Authorisation Holder of the SmPC states "KPharma Limited" with the address "12 Secret **Av**, London".

- The organisation name as stated in the SmPC is not present in the XEVMPD look-up table/available Controlled Vocabulary (CV) list "eXtended Eudravigilance Product Dictionary (XEVMPD) organisations".
- Organisation "KPharma Limited" with the address "12 Secret **Avenue**, London" is available with EV Code "ORG0001". It is the same legal entity.

"ORG0001" should therefore be referenced in the applicable AMP.

It is not necessary to create a new MAH organisation entity with the name and address "KPharma Limited" with the address "12 Secret **Av**, London".

All AMPs for which "KPharma Limited" with the address "12 Secret **Av**, London" is the MAH as per the corresponding SmPC should reference "ORG0001" with the address "12 Secret **Avenue**, London".

Scenario 3:

Section 7. Marketing Authorisation Holder of the SmPC states "KPharma **Limited**" with the address "12 Secret **Av**, London".

- The organisation name as stated in the SmPC is not present in the XEVMPD look-up table/available Controlled Vocabulary (CV) list .
- Organisation "KPharma **Ltd.**" with the address "12 Secret **Avenue**, London" is available with EV Code "ORG0002".

As the most complete information on the organisation name /address should be provided, the maintenance process described in section [2.2. Maintenance of a marketing authorisation holder \(MAH\) organisation entity](#) of this document should be followed to update the existing organisation entity with EV Code "ORG0002" to amend the name and address to "KPharma **Limited**" with the address "12 Secret **Avenue**, London".

All AMPs referencing the MAH organisation entity with the assigned EV Code "ORG0002" will automatically reference the organisation with the complete address and name.

MAH Organisation element structure:

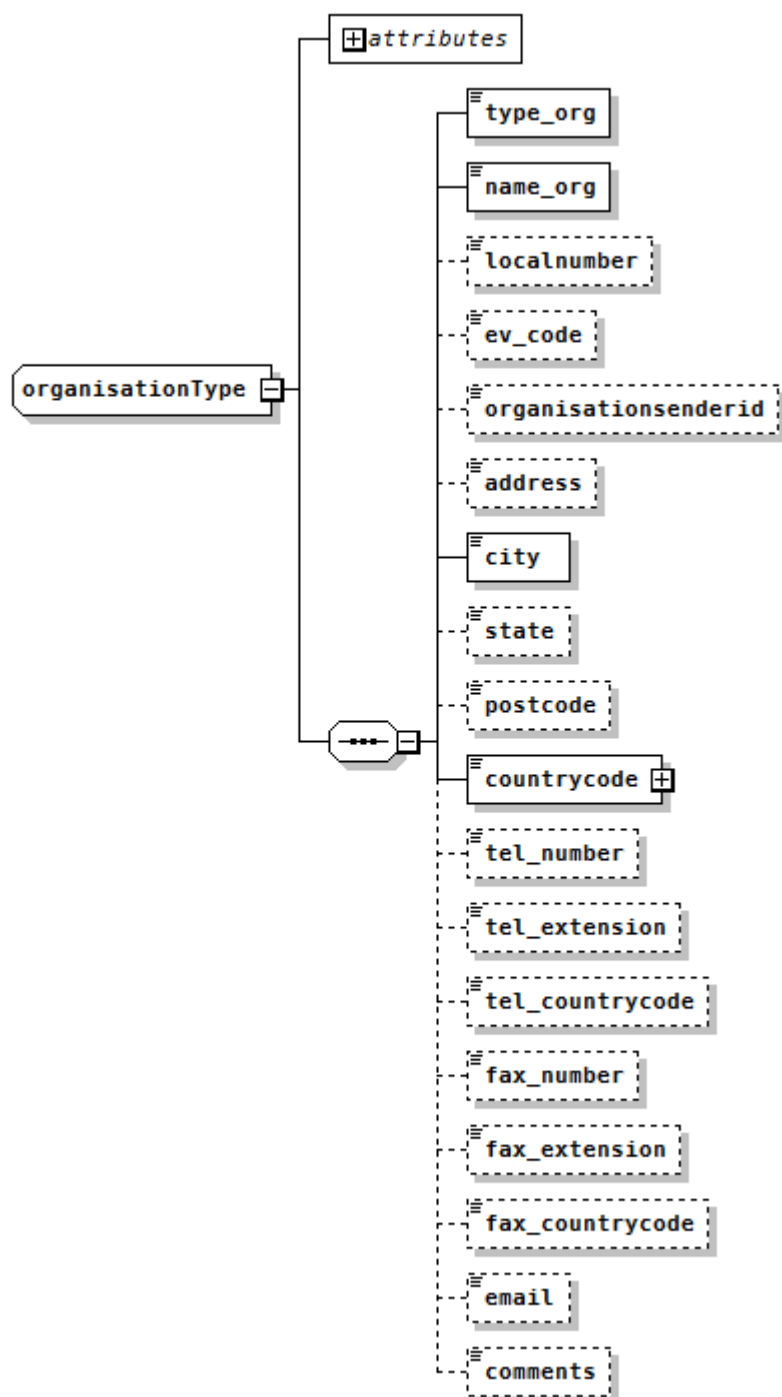


Table 4 - Art 57(2) data elements requirements overview for MAH organisation submission

Reference Code	Schema Field Name	EVWEB Field Label	Rules for Art 57(2) submission:	Guidance Link
M - Mandatory M*- Mandatory with conditions O – Optional				
	Organisation element structure <i>O Organisation</i>			
@ O..1	(@) operationtype		M	Insert (1) Update (2) Nullification (4) as applicable
O.1	type_org	Type	M	1.6.1.
O.2	name_org	MAH name	M	1.6.2.
O.3	localnumber		M*	1.6.3.
O.4	ev_code	EV code	M*	1.6.4.
O.5	organisationsenderid	MAH sender ID	O	1.6.5.
O.6	address	Address	M*	1.6.6.
O.7	City	City	M	1.6.7.
O.8	state	Region	O	1.6.8.
O.9	postcode	Postcode	M*	1.6.9.
O.10	countrycode	Country code	M	1.6.10.
O.11	tel_number	Tel Number	O	1.6.11.
O.12	tel_extension	Tel Extension	O	1.6.11.
O.13	tel_countrycode	Tel Country code	O	1.6.11.
O.14	fax_number	Fax Number	O	1.6.12.
O.15	fax_extension	Fax Extension	O	1.6.12.
O.16	fax_countrycode	Fax Country Code	O	1.6.12.
O.17	email	E-mail address	O	1.6.13.
O.18	comments	Comment	M*	1.6.14.
O.19	sme_status	SME Status	M	1.6.15.
O.20	sme_number	SME Number	O	1.6.16.

1.6.1. Type of organisation (O.1)

The type of organisation must be specified - Marketing Authorisation Holder (MAH) = 1, Sponsor = 2.

Only organisation set as MAH can be referenced in an AMP entity.

1.6.2. Organisation name (O.2)

The name of the organisation (MAH) by means of the legal entity of the medicinal product must be specified as indicated in section 7. Marketing Authorisation Holder of the SmPC.

See NOTE 14 for related information.

1.6.3. Local Number (O.3)

Local number is a unique reference number that must be assigned for an organisation entity in the XEVPRM following an operation type 'Insert' (1).

When a marketing authorisation holder (MAH) organisation is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to this MAH organisation. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to retrieve the corresponding EV Code.

EXAMPLE: XEVPRM – Insert of MAH Organisation

```
- <organisations>
- <organisation operationtype="1">
  <type_org>1</type_org>
  <name_org>Example MAH</name_org>
  <localnumber>3</localnumber>
  <address>7 Westferry Circus</address>
  <city>London</city>
  <postcode>E14 4HB</postcode>
  <countrycode>GB</countrycode>
  </organisation>
</organisations>
</evprm>
```

EXAMPLE: XEVPRM Acknowledgement – Insert of MAH Organisation

```
- <reportacknowledgment>
  <reportname>ORGANISATION</reportname>
  <localnumber>3</localnumber>
  <ev_code>ORGXXXX</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc> </reportacknowledgment>
```


1.6.4. EV Code (O.4)

The EudraVigilance (EV) Code of the MAH organisation must be specified if the operation type is NOT an 'Insert'.

I.e. if maintenance related operations are performed on an MAH organisation entity successfully inserted in the XEVMPD, the EV Code of the MAH organisation entity must be referenced in this field).

1.6.5. Organisation Sender Identifier (O.5)

The ID of the organisation that corresponds to the same organisation as assigned in the EudraVigilance registration system may be provided.

1.6.6. Address (O.6)

The address of the MAH must be specified as stated in section 7. Marketing Authorisation Holder of the SmPC.

1.6.7. City (O.7)

The city of the MAH must be specified as stated in section 7. Marketing Authorisation Holder of the SmPC.

1.6.8. State (O.8)

The state (region) of the MAH may be specified as stated in section 7. Marketing Authorisation Holder of the SmPC.

1.6.9. Postcode (O.9)

The postcode of the MAH must be specified as stated in section 7. Marketing Authorisation Holder of the SmPC.

1.6.10. Country Code (O.10)

The country code of the MAH must be specified as stated in section 7. Marketing Authorisation Holder of the SmPC.

The country code is to be specified using the ISO-3166-1 standard. The official list of ISO 3166-1 country codes is maintained by the International Organization for Standardization (ISO).

- The country code "GR" corresponding to "Greece" should be used for locations in Greece.

- The country code "GB" corresponding to "United Kingdom" should be used for locations in England, Wales, and Scotland.
- The country code "XI" corresponding to "United Kingdom (Northern Ireland)" should be used for locations in Northern Ireland.

1.6.11. Telephone number (O.11)/Extension (O.12)/Country Code (O.13)

The telephone number, extension and telephone country code may be specified.

1.6.12. Fax number (O.14)/Extension (O.15)/Country Code (O.16)

The fax number, extension and fax country code may be specified.

1.6.13. Email address (O.17)

The email address of a contact point authorised for communication with the EMA on behalf of the marketing authorisation holder shall be specified.

This communication may involve procedural regulatory matters (e.g. notification of non-pharmacovigilance referrals).

1.6.14. Comment (O.18)

Further information on the organisation may be provided in the comment field, if required.

When operation type 'Nullification' (4) is performed on an organisation entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

See section [2.2. Maintenance of a marketing authorisation holder \(MAH\) organisation entity](#) for related information.

1.6.15. SME status (O.19)

The SME status applicable to the MAH organisation must be selected.

The following values are available:

- N/A (1) – to be used by non-SMEs;
- Micro (2);
- Small (3);
- Medium (4).

The definitions for medium, small and micro sized enterprises (SME) are laid down in [Commission Recommendation 2003/361/EC](#):

- Micro enterprises – with less than 10 employees and an annual turnover or balance sheet total of not more than € 2 million;
- Small enterprises – with less than 50 employees and an annual turnover or balance sheet total of not more than € 10 million.
- Medium enterprises – with less than 250 employees and an annual turnover of not more than € 50 million or balance sheet total of not more than € 43 million.

SMEs must also meet the following criteria:

They must be located in the EEA;

They must declare any partner or linked enterprise in the ownership structure of the enterprise.

It remains the responsibility of the MAHs to ensure that the information on the size of the organisation is accurate.

Companies are advised to verify the status of their company as a micro, small or medium enterprise by sending a declaration directly through to the Agency's SME office.

To keep administrative burden on companies to a minimum, the Agency uses the European Commission's model declaration, which has been designed to promote the application of Commission Recommendation 2003/361/EC on the definition of SMEs.

The verification of the SME status by the SME office can be performed in parallel with the update of product entries by MAHs. The SME number obtained as a result of the verification process may be submitted at a later date with the continual update of product changes by MAHs.

Micro- and small-sized enterprises which had their status verified in order to benefit from the EudraVigilance fee waiver MedDRA subscription are advised to renew their SME status as applicable.

Further information on how to register as a SME is available on the [SME Office area of the EMA website](#).

The Agency actively monitors the SME status of companies. The Agency reserves the right to request further information from MAHs to establish that the SME criteria are met.

1.6.16. SME number (O.20)

The SME number may be provided if available.

When all of the above fields required for the submission of an MAH organisation are specified as applicable, and following a successful submission in the XEVMPD, a local code will be assigned as an internal reference code until an EV Code has been provided as part of the acknowledgement process.

Following a successful insert, an EV Code for the MAH Organisation entity will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for an Organisation is 'ORG' followed by a number.

1.7. Initial submission of an ATC Code

New ATC Code must be submitted in the XEVMPD as "proposed term" in an XEVPRM with the operation type 'Insert (1)'.

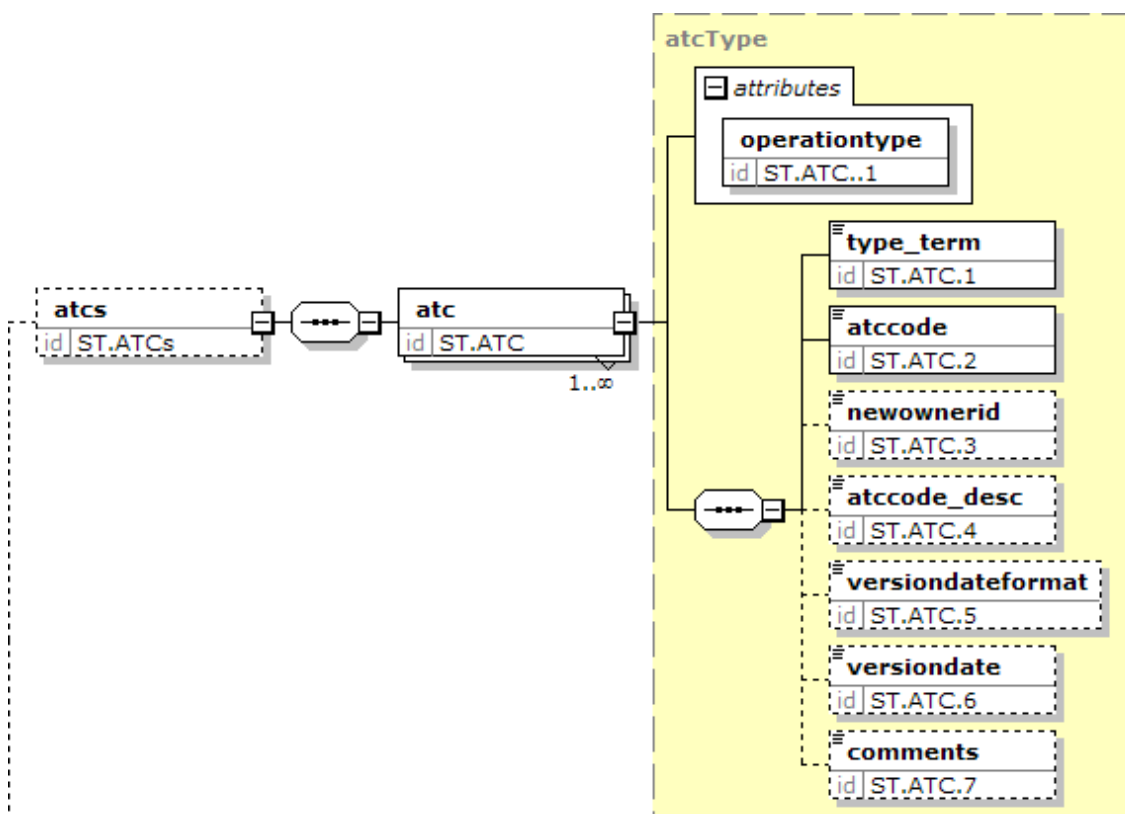
A list of standard ATC Codes is maintained in the XEVMPD by the Agency and can be obtained from the [WHO Collaborating Centre for Drug Statistics Methodology](#).

Marketing authorisation holders can submit only proposed ATC Codes in the XEVMPD. The ATC Code section of the XEVPRM should be used (as described in Table 21. Standard Terms – ATC elements of Chapter 3.I of the Detailed Guidance). The type of the term is equal to 2 (Proposed Term).

All five levels of the ATC code can be used. The most specific ATC code in relation to the medicinal product needs to be specified.

The proposed ATC Code must not match a current standard ATC Code in the XEVMPD.

ATC Code elements structure:



EXAMPLE: XEVPRM – Insert of a proposed ATC Code

```
= <standardterminology>
= <atcs>
= <atc.operationtype="1">
  <type_term>2</type_term>
  <atccode>N02BE61</atccode>
  <atccode_desc>Paracetamol, Combinations with caffeine</atccode_desc>
</atc>
```

EXAMPLE: XEVPRM Acknowledgement – Insert of a proposed ATC Code

```
= <reportacknowledgment>
  <reportname>ATCCODE</reportname>
  <localnumber>N02BE61</localnumber>
  <ev_code>N02BE61</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
    <operationresultdesc>Entity inserted successfully</operationresultdesc>
  </reportacknowledgment>
= </reportacknowledgment>
```

1.7.1. Type Term (ST.ATC.1)

The type of term must be specified.

The following values are available:

- Development Term (1): can only be used in Development product entries;
- Proposed (2): to be referenced in Authorised and/or Development product entries;
- Standard Term (3): available to EMA only.

1.7.2. ATC Code (ST.ATC.2)

The ATC Code must be specified.

The proposed ATC Code must not match a current standard ATC Code in the XEVMPD.

1.7.3. New owner ID (ST.ATC.3)

Available for EMA use only.

1.7.4. ATC Code description (ST.ATC.4)

The ATC code description in English must be specified.

EXAMPLES – ATC Code description: "tetracycline"; "oxytetracycline, combinations"; "central nervous system"

1.7.5. Version Date Format (ST.ATC.5)

Format of the version date should correspond to "102" for "CCYYMMDD".

1.7.6. Version Date (ST.ATC.6)

The date of the last update of the specified ATC code may be specified.

1.7.7. Comment (ST.ATC.7)

Further information on the ATC Code may be provided in the comment field, if required.

When operation type 'Nullification' (4) is performed on a proposed/development ATC Code entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

When all of the above fields required for the submission of an ATC Code are specified as applicable, and following a successful insert in the XEVMPD, an EV Code for the ATC Code will be received in the XEVPRM Acknowledgement.

1.8. Initial submission of an authorised/administrable pharmaceutical form

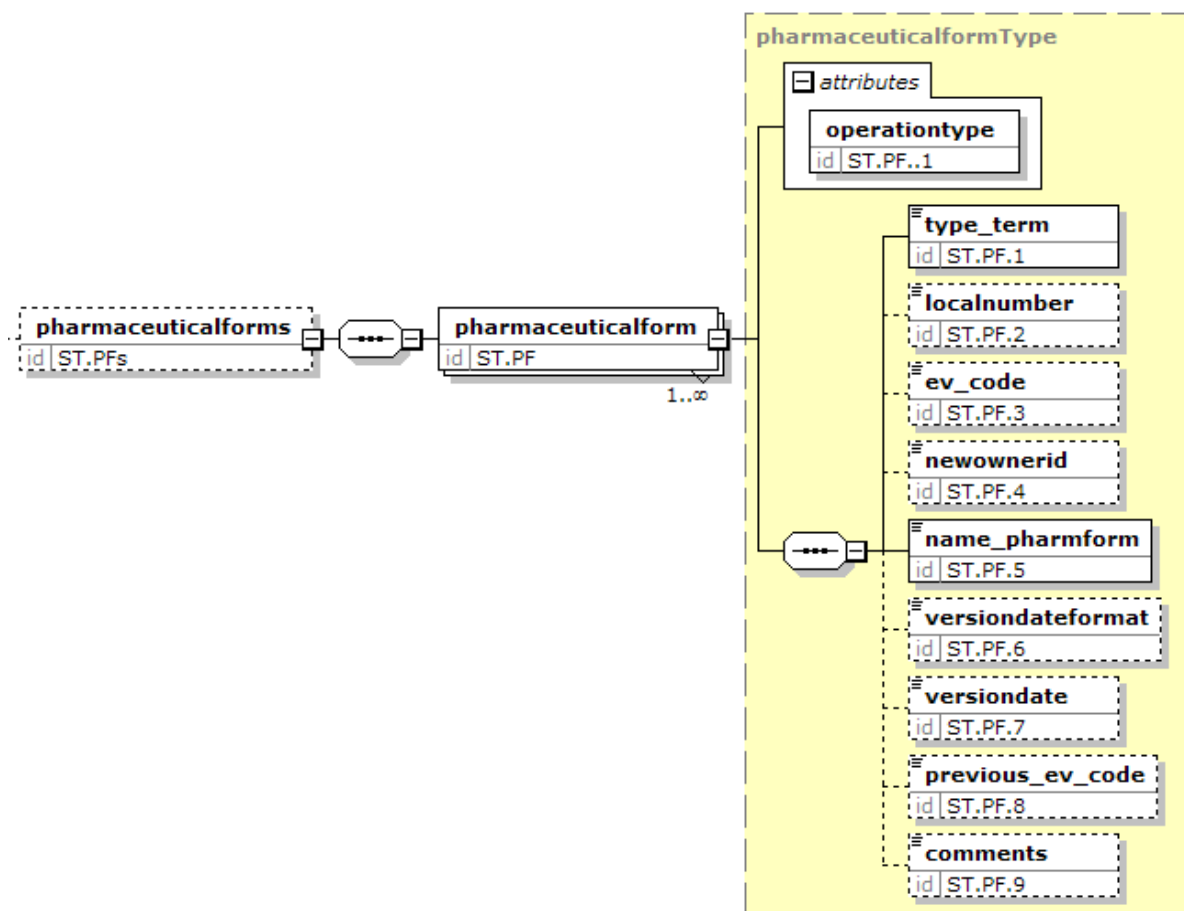
New pharmaceutical form must be submitted in the XEVMPD as a "proposed term" in an XEVPRM with the operation type 'Insert (1)'.

Prior to submitting a new proposed pharmaceutical form in the XEVMPD, marketing authorisation holders are advised to consult the spread sheet "**Re-mapped_PDFs**" included in the published Controlled Vocabulary list "*Extended EudraVigilance product report message (XEVMPD) pharmaceutical dose forms*" available at the [Agency's website](#) to determine if a standard pharmaceutical form could be used instead of the intended proposed pharmaceutical form.

In the context of improvement of the XEVMPD Controlled Vocabulary data quality and following a consultation with EDQM, some proposed Pharmaceutical Forms have been re-mapped to Standard pharmaceutical forms in the XEVMPD production system.

If the required pharmaceutical form does not exist in the XEVMPD as a standard or a proposed term, the pharmaceutical form should be provided as "proposed term" in the XEVPRM with the operation type 'Insert'. The Pharmaceutical form section of the XEVPRM should be used (as described in Table 23. Standard Terms – Pharmaceutical Form elements of Chapter 3.I of the Detailed Guidance). The type of the term is equal to 2 (Proposed Term).

Pharmaceutical form element structure:



1.8.1. Type Term (ST.PF.1)

The type of term must be specified.

The following values are available:

- Development Term (1): can only be used in Development product entries
- Proposed (2): to be referenced in Authorised and Development product entries
- Standard Term (3): available to EMA only

1.8.2. Local Number (ST.PF.2)

Local number is a unique reference number that must be assigned for a pharmaceutical form entity in the XEVPRM following an operation type 'Insert' (1).

When a pharmaceutical form is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to this pharmaceutical form entity. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to identify the corresponding EV Code.

EXAMPLE: XEVPRM – Insert of a proposed pharmaceutical form

```
- <standardterminology>  
- <pharmaceuticalforms>  
- <pharmaceuticalform operationtype="1">  
  <type_term>2</type_term>  
  <localnumber>6</localnumber>  
  <name_phamform>Example PDF</name_phamform>  
</pharmaceuticalform>  
</pharmaceuticalforms>  
</standardterminology>  
</evprm>
```

EXAMPLE: XEVPRM Acknowledgement – Insert of a proposed pharmaceutical form

```
- <reportacknowledgment>  
  <reportname>PHARMACEUTICALFORM</reportname>  
  <localnumber>6</localnumber>  
  <ev_code>PHF123</ev_code>  
  <operationtype>1</operationtype>  
  <operationresult>2</operationresult>  
    <operationresultdesc>Entity inserted successfully</operationresultdesc>  
  </reportacknowledgment>  
</acknowledgment>  
</evprmack>
```

1.8.3. EV Code (ST.PF.3)

EudraVigilance (EV) Code of the pharmaceutical form must be specified if the operation type is NOT an 'Insert'.

I.e. if maintenance related operations are performed on a pharmaceutical form entity successfully inserted in the XEVMPD, the EV Code of the pharmaceutical form entity must be referenced in this field.

1.8.4. New owner ID (ST.PF.4)

This field is available for EMA use only.

1.8.5. Name of the Pharmaceutical Form (ST.PF.5)

The name of the pharmaceutical form in English must be specified.

EXAMPLES - Pharmaceutical Form name: tablet, capsule

1.8.6. Version Date Format (ST.PF.6)

Format of the version date should correspond to "102" for "CCYYMMDD".

1.8.7. Version Date (ST.PF.7)

The date of the last update of the specified pharmaceutical form code may be specified.

1.8.8. Previous EV Code (ST.PF.8)

For a Proposed pharmaceutical form Term, this field may be used to make a reference to the EV Code of the Development pharmaceutical form Term if previously submitted in the XEVMPD.

For a Development Term this field is not applicable.

1.8.9. Comment (ST.PF.9)

Further information on the pharmaceutical form may be provided in the comment field, if required.

When operation type 'Nullification' (4) is performed on a proposed/development pharmaceutical form entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

Following a successful insert, an EV Code for the pharmaceutical form entity will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for a pharmaceutical form is 'PDF' followed by a number.

1.9. Initial Submission of a route of administration (RoA)

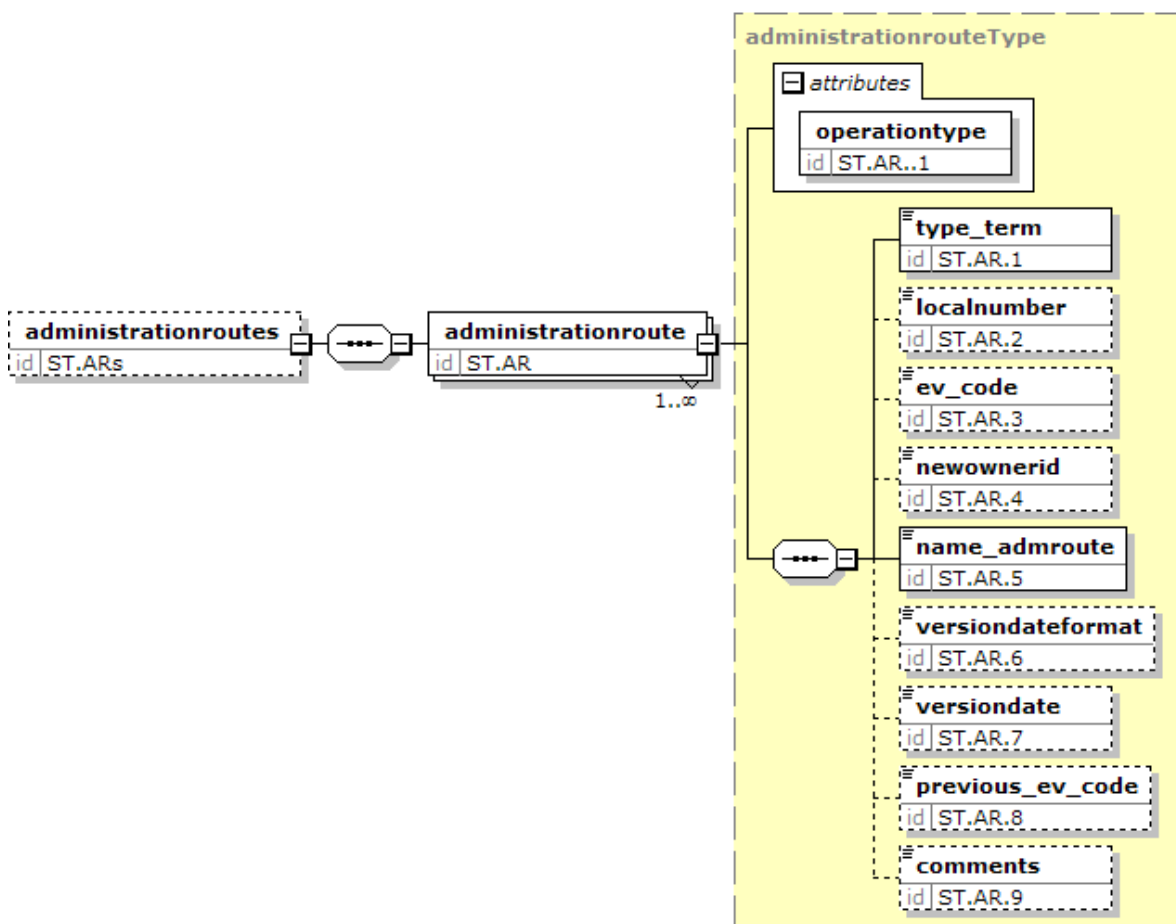
New route of administration must be submitted in the XEVMPD as a "proposed term" in an XEVPRM with the operation type 'Insert (1)'.

Prior to submitting a new proposed route of administration in the XEVMPD, marketing authorisation holders are advised to consult the spread sheet "**Re-mapped_RoA**" included in the published Controlled Vocabulary list "*Extended EudraVigilance product report message (XEVMPD) routes of administration*" available at the [Agency's website](#) to determine if a standard RoA could be used instead of the intended proposed RoA.

In the context of improvement of the XEVMPD Controlled Vocabulary data quality and following a consultation with EDQM, some proposed Routes of Administration have been re-mapped to Standard RoA in the XEVMPD production system.

If the required route of administration does not exist in the XEVMPD as a standard or a proposed term, the route of administration route should be provided as "proposed term" in the XEVPRM with the operation type 'Insert' (1). The Administration route section of the XEVPRM should be used (as described in Table 25. Standard Terms – Administration Route elements of Chapter 3.I of the Detailed Guidance). The type of the term is equal to 2 (Proposed Term).

Administration route element structure:



1.9.1. Type Term (ST.AR.1)

The type of term must be specified.

The following values are available:

- Development Term (1): can only be used in Development product entries
- Proposed (2): to be referenced in Authorised and Development product entries
- Standard Term (3): available to EMA only

1.9.2. Local Number (ST.AR.2)

Local number is a unique reference number that must be assigned for a RoA entity in the XEVPRM following an operation type 'Insert' (1).

When a RoA is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to this RoA entity. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to identify the corresponding EV Code.

EXAMPLE: XEVPRM – Insert of a proposed route of administration

```
- <standardterminology>
- <administrationroutes>
- <administrationroute operationtype="1">
  <type_term>2</type_term>
  <localnumber>7</localnumber>
  <name_admroute>Example RoA</name_admroute>
</administrationroute>
</administrationroutes>
</standardterminology>
</evprm>
```

EXAMPLE: XEVPRM Acknowledgement– Insert of a proposed route of administration

```
- <reportacknowledgment>
  <reportname>ADMINISTRATIONROUTE</reportname>
  <localnumber>7</localnumber>
  <ev_code>ADR618</ev_code>
  <operationtype>1</operationtype>
  <operationresult>2</operationresult>
  <operationresultdesc>Entity inserted successfully</operationresultdesc>
</reportacknowledgment>
```

1.9.3. EV Code (ST.AR.3)

EudraVigilance (EV) Code of the RoA must be specified if the operation type is NOT an 'Insert'.

I.e. if maintenance related operations are performed on a RoA entity successfully inserted in the XEVMPD, the EV Code of the RoA entity must be referenced in this field.

1.9.4. New owner ID (ST.AR.4)

This field is available for EMA use only.

1.9.5. Name of the Route of Administration (ST.AR.5)

The name of the route of administration in English must be specified.

EXAMPLES – Route of administration name: Oral use, Subcutaneous use

1.9.6. Version Date Format (ST.AR.6)

Format of the version date should correspond to "102" for "CCYYMMDD".

1.9.7. Version Date (ST.AR.7)

The date of the last update of the specified route of administration code may be specified.

1.9.8. Previous EV Code (ST.AR.8)

For a Proposed (RoA) Term, this field may be used to make a reference to the EV Code of the Development (RoA) Term if previously submitted in the XEVMPD.

For a Development Term this field is not applicable.

For a Standard Term this field should refer to the EV Code of the previous Proposed or Development Term.

1.9.9. Comment (ST.AR.9)

Further information on the RoA may be provided in the comment field, if required.

When operation type 'Nullification' (4) is performed on a proposed/development RoA entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

Following a successful insert, an EV Code for the Route of Administration entity will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for a route of administration is 'ADR' followed by a number.

1.10. Submission of an attachment

An attachment is any allowed file that is sent in the zip file containing the XEVPRM message with the information:

- For medicinal products, Printed Product Information (PPI) must be submitted as an attachment;
- For substances, Printed Substance Information (PSI) may be submitted as an attachment in an Art57 helpdesk (see section [1.4. Initial submission of an approved substance](#) of this document for related information).

Format of an attachment

Attachments can be provided in the following formats: .PDF, .DOC, .DOCX, .XLS and .XLSX.

- The allowed file types for PPI (i.e. SmPC/PIL/marketing authorisation decision) are: .PDF (1), .DOC (2), .DOCX (3).
- The allowed file types for PSI (i.e. substance information) are .PDF (1), .DOC (2), .DOCX (3), XLS (4) and .XLSX (5).

Marketing authorisation holders are not to send PDF scanned documents (except for documents granting or renewing marketing authorisation), but need to provide "genuine" PDF documents.

For PDF attachments, PDF file version 1.4 or 1.7 should be used as these are the only two versions that are ISO standards compliant. They are used for long term preservation of information and therefore the Agency/MAHs will have the assurance that we will be able to open them for many years.

Content of an attachment

A copy of the SmPC as authorised by the Authorising Body should be provided.

In case where the approved SmPC does not state an authorisation number, a date of authorisation/renewal or the MAH, a copy of the document granting or renewing marketing authorisation should also be provided as an additional PPI attachment.

Where, in exceptional circumstances, the SmPC is not available as part of the marketing authorisation, an equivalent document that facilitates the data quality assurance process by the Agency (e.g. English common text, PIL or other similar text as authorised by the Authorising Body) should be provided.

Content of attachments cannot be updated. Updated attachment(s) must be resubmitted when necessary in the context of the data maintenance submission, i.e. when the variations lead to changes to the sections of the SmPC as highlighted in section of this document for further information.

Only the latest version of the SmPC for a medicinal product is retrievable/visible by the user. Non-current PPI versions will be archived.

NOTE 15

- In Member States with more than one official language(s), where medicinal product information is available in more than one language(s) and the corresponding SmPC/Patient Information Leaflet (PIL)/other similar text as authorised by the Authorising Body is therefore available in such language(s), the medicinal product should be submitted in the XEVMPD for each of the available language(s). The Printed Product Information (PPI) attached to each of the AMP entity/entities should correspond to the applicable language(s).

List of official languages per country can be found on the [Agency's website](#).

See also

Table 1b - Requirements for AMP records and attachments for countries with more than one national language for related information.

- In member states where an SmPC in the national language might not be available, the text from another Member State may be used (e.g. Belgian SmPC is accepted in Luxembourg, therefore AMP authorised in Luxembourg can contain the Belgium SmPC as an attachment). *See EXAMPLE 69*.
- For centrally authorised products, the SmPC to be used for reference must be in English.

Attachment information can be added using the attachment section of the XEVPRM (see Table 61. Attachment elements of Chapter 3.I of the Detailed Guidance for further information).

It is not possible to submit a standalone PPI unless it is submitted in a Gateway solution or EV Post functionality. **The PPI attachment must be referenced in at least one product entity submitted in the same XEVPRM in EVWEB.**

EXAMPLE 66 - Belgium

Medicinal product "Skyprod® 250 mg/ml, oplossing voor injectie" is authorised in Belgium with the authorisation number "BE12345".

The Federal Agency for Medicines and Health Products has authorised the SmPC in French and Dutch, the patient information leaflet is available in French, Dutch and German.

Three AMP entities should be therefore submitted in the XEVMPD, one entity for each of the official languages (Dutch, French and German). The relevant PPI attachment must be referenced in the corresponding AMP entity:

AMP entity 1:

PPI to be attached = SmPC in Dutch

"Authorisation country code" (AP.12.1) =	Belgium (BE)
"Authorisation number" (AP.12.4) =	BE12345
"Full Presentation Name" (AP.13.1) =	Skyprod® 250 mg/ml, oplossing voor injectie
"Product Short Name" (AP.13.2) =	Skyprod

"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	250 mg/ml
"Product Form Name" (AP.13.6) =	oplossing voor injectie

AMP entity 2:

PPI to be attached = SmPC in French

"Authorisation country code" (AP.12.1) =	Belgium (BE)
"Authorisation number" (AP.12.4) =	BE12345
"Full Presentation Name" (AP.13.1) =	Skyprod® 250 mg/ml, solution injectable
"Product Short Name" (AP.13.2) =	Skyprod
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	250 mg/ml
"Product Form Name" (AP.13.6) =	solution injectable

AMP entity 3:

PPI to be attached = PIL in German

"Authorisation country code" (AP.12.1) =	Belgium (BE)
"Authorisation number" (AP.12.4) =	BE12345
"Full Presentation Name" (AP.13.1) =	Skyprod® 250 mg/ml, Injektionslösung
"Product Short Name" (AP.13.2) =	Skyprod
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	250 mg/ml
"Product Form Name" (AP.13.6) =	Injektionslösung

EXAMPLE 67 - Malta

Medicinal product "Rydimprod 80 mg tablets" is authorised in Malta with the authorisation number "MA123/4567".

The Maltese NCA has authorised the SmPC in English only.

Although there are two official languages in Malta (Maltese and English), only one AMP entity should be submitted in the XEVMPD, because the Maltese NCA has authorised the SmPC and PIL in English only.

PPI to be attached = SmPC in English

"Authorisation country code" (AP.12.1) =	Malta (MT)
"Authorisation number" (AP.12.4) =	MA123/4567
"Full Presentation Name" (AP.13.1) =	Rydimprod 80 mg tablets

"Product Short Name" (AP.13.2) =	Rydimprod
"Product INN/Common Name" (AP.13.3) =	<this field should be left blank>
"Product Company Name" (AP.13.4) =	<this field should be left blank>
"Product Strength Name" (AP.13.5) =	80 mg
"Product Form Name" (AP.13.6) =	tablets

EXAMPLE 68 - Finland

In Finland, there are two official languages. The SmPCs for medicinal products authorised in the national procedure exist only in Finnish. Patient Information Leaflets are available in Finnish and Swedish.

Therefore, for medicinal product authorised in Finland in NAP/MRP/DCP, two AMP entities should be submitted to the XEVMPD:

AMP entity 1:

PPI to be attached = SmPC in Finnish

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in section 1. Name of the medicinal product of the corresponding SmPC (i.e. in Finnish). The substance name(s) are also to be specified as reflected in the SmPC (i.e. in Finnish).

AMP entity 2:

PPI to be attached = Patient Information Leaflet in Swedish

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in the corresponding Patient Information Leaflet (i.e. in Swedish). The substance name(s) are also to be specified as reflected in the Patient Information Leaflet (i.e. in Swedish).

EXAMPLE 69 - Luxembourg

In Luxembourg, there are three official languages (French, German and Luxembourgish).

Since SmPCs/PILs of medicinal products authorised in Belgium/Germany/Austria are accepted in Luxembourg, an AMP authorised in Luxembourg can contain the SmPC/PIL of an AMP authorised in Belgium/Germany/Austria as an attachment.

Scenario 1 – MAH submits to the Luxembourgish Authority a Belgian SmPC in French as well as PIL in German.

Two AMP entities should be submitted in the XEVMPD:

AMP entity 1:

PPI to be attached = SmPC in French

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in section 1. Name of the medicinal product of the corresponding SmPC

(i.e. in French). The substance name(s) are also to be specified as reflected in the SmPC (i.e. in French).

AMP entity 2:

PPI to be attached = Patient Information Leaflet in German

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in the corresponding Patient Information Leaflet (i.e. in German). The substance name(s) are also to be specified as reflected in the Patient Information Leaflet (i.e. in German).

Scenario 2 – MAH submits to the Luxembourgish Authority a Belgian SmPC in French.

One AMP entity should be submitted in the XEVMPD:

AMP entity 1:

PPI to be attached = SmPC in French

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in section 1. Name of the medicinal product of the corresponding SmPC (i.e. in French). The substance name(s) are also to be specified as reflected in the SmPC (i.e. in French).

Scenario 3 - MAH submits to the Luxembourgish Authority an Austrian SmPC in German.

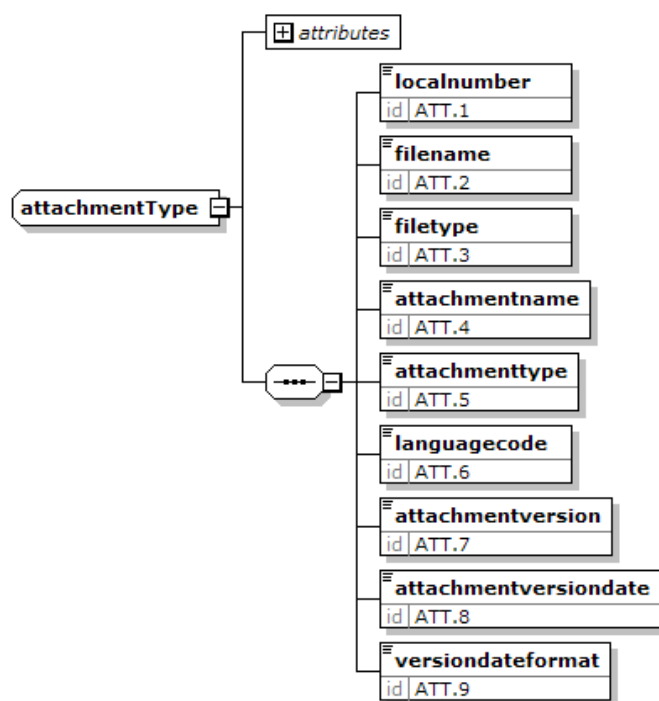
One AMP entity should be submitted in the XEVMPD:

AMP entity 1:

PPI to be attached = SmPC in German

The presentation name elements in data fields AP.13.1 - AP.13.6 must be entered based on the medicinal product name stated in section 1. Name of the medicinal product of the corresponding SmPC (i.e. in German). The substance name(s) are also to be specified as reflected in the SmPC (i.e. in German).

Attachment element structure:



1.10.1. Local number (ATT.1)

Local number is a unique reference number that must be assigned for an attachment entity in the XEVPRM following an operation type 'Insert' (1).

When an attachment is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to this attachment entity. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to identify the corresponding EV Code.

1.10.2. File name (ATT.2)

The file name of the attachment with file extension must be specified.

The file name for the attachment can be assigned by the marketing authorisation holder; there is no naming convention to be followed. Non-ASCII characters are not allowed for the attachment file name.

1.10.3. File type (ATT.3)

The file type of the attachment must be specified as applicable.

The allowed file types for PPI (i.e. SmPC/PIL/marketing authorisation decision) are: .PDF (1), .DOC (2), .DOCX (3).

The allowed file types for PSI (i.e. substance information) are .PDF (1), .DOC (2), .DOCX (3), .XLS (4) and .XLSX (5).

1.10.4. Attachment name (ATT.4)

The name of the attachment given by the sender should be specified.

1.10.5. Attachment type (ATT.5)

The type of attachment must be specified.

Allowed values are:

- Printed Product Information (PPI) = 1
- Printed Substance Information (PSI) = 2

1.10.6. Language code (ATT.6)

The code of the language (of the attachment) must be specified (using the "LANGUAGE" reference list).

1.10.7. Attachment version (ATT.7)

The version of the PPI/PSI attachment must be specified.

The version number and version date refer to the 'internal' reference of the marketing authorisation holder and do not need to appear on the physical document (i.e. the SmPC document attached). The version number and version date allow the Agency to understand if the version of the SmPC has changed over time.

Where the version date is reflected on the physical document, it should be reflected as presented in the SmPC Section 10. Date of revision of text.

1.10.8. Attachment version date (ATT.8)

The date of the last update of the PPI/PSI document must be specified.

The version number and version date refer to the 'internal' reference of the marketing authorisation holder and do not need to appear on the physical document (i.e. the SmPC document attached). The version number and version date allow the Agency to understand if the version of the SmPC has changed over time.

Where the version date is reflected on the physical document, it should be reflected as presented in the SmPC Section 10. Date of revision of text. When the date is not stated in the physical document, the date when the SmPC has been approved by the NCA can be provided.

1.10.9. Version date format (ATT.9)

The value must be "102" for "CCYYMMDD".

Following a successful insert, an EV Code for the attachment entity will be received in the XEVPRM Acknowledgement.

The pattern of the EV Code for an attachment is 'ATT' followed by a number.

1.11. Initial submission of a Pharmacovigilance System Master File (PSMF) information

The information on the marketing authorisation holder's Pharmacovigilance System Master File must be submitted using the Master File Location section of an XEVPRM with operation type 'Insert' (1).

The Pharmacovigilance system master file definition is provided in Article 1(28e) of Directive 2001/83/EC and the minimum requirements for its content and maintenance are set out in the Commission Implementing Regulation (EU) No 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC (the Implementing Regulation is referenced as IR). The detailed requirements provided by the Commission Implementing Regulation are further supported by the guidance in the [Guideline on good pharmacovigilance practices \(GVP\): Module II – Pharmacovigilance system master file](#):

- *The PSMF shall be located within the EU, either at the site where the main pharmacovigilance activities are performed or at the site where the qualified person responsible for pharmacovigilance operates [IR Art 7(1)], irrespective of the format (paper-based or electronic format file). Following European Economic Area (EEA) agreements, the PSMF may also be located in Norway, Iceland or Liechtenstein.*
- *At the time of marketing authorisation application, the applicant should submit electronically the PSMF location information using the agreed format [IR Art26 1(a)], and subsequently include in the application, the PSMF reference number, which is the unique code assigned by the EudraVigilance (EV) system to the master file when the EudraVigilance Medicinal Product Report Message (XEVPRM) is processed. Further to the granting of a marketing authorisation, the PSMF will be linked by the marketing authorisation holder to the EVMPD product code(s). All PSMFs must be registered in the Article 57 database.*
- *The required location information for the PSMF is a physical office address of the marketing authorisation holder or a contracted third party. Where the PSMF is held in electronic form, the location stated must be a site where the data stored can be directly accessed, and this is sufficient in terms of a practical electronic location [IR Art 7(3)].*

For the purpose of the Article 57(2) notifications on the PSMF location, the following should be taken into account:

- In accordance with Article 3 of Regulation (EU) NO 1235/2010 (the pharmacovigilance legislation), the obligation on the part of the MAHs to maintain and make available on request a Pharmacovigilance System Master File (PSMF) will apply "... to marketing authorisations granted before 2 July 2012 as from either:
 - (a) the date on which those marketing authorisations are renewed; or
 - (b) the expiry of a period of 3 years starting from 2 July 2012,whichever is the earlier.

Therefore from 2 July 2015 MAHs are required to submit the Pharmacovigilance System Master File information to the Article 57 database (aka XEVMPD).

- To request an EV Code for a PSMF, the following three characteristics need to be taken into account:

- i. The marketing authorisation holder (MAH) as a legal entity
- ii. The location of the PSMF
- iii. The Pharmacovigilance System (PS)

The following case scenarios provide explanations, as to when and how an EV Code for a PSMF needs to be requested by the same marketing authorisation holder:

Table 5 – Requesting a single/multiple PSMF EV Code(s) by the same MAH

	Scenario 1	Scenario 2	Scenario 3
MAH	Same	Same	Same
Location	Same	Same	Different
PV System	Same	Different	Different
Number of EV Codes to request	1	>1	>1
Comment (MF.11) field information	Not required	Not required	Not required

- Scenario 1:
 - MAH A has a PSMF location D for the PV system X and therefore submits one PSMFL entity in the Article 57 database; one PSMFL EV Code is assigned.
- Scenario 2:
 - MAH A has two **different PV systems** Y and Z, each with a separate PSMF in the **same location** R. MAH A shall submit two PSMFL entities in the Article 57 database/XEVMPD; two PSMFL EV Codes will be assigned:
 - 1/ one EV Code will be assigned for the PV System Y and corresponding PSMF at location R; and
 - 2/ another EV Code will be assigned for the PV System Z and corresponding PSMF at the same location R.
- Scenario 3:
 - MAH A has **different PV systems** Y and Z, each with a separate PSMF in **different locations** R and S. MAH A shall submit two PSMFL entities in the Article 57 database; two PSMFL EV Codes will be assigned:
 - 1/ one for the PV System Y and corresponding PSMF at location R; and
 - 2/ one for the PV System Z and corresponding PSMF at location S.

In the context of the requirement set out in Article 8(3) of the Directive 2001/83/EC related to the submission of the summary of the PV system information and the requirement to submit electronically the PSMF location information within the XEVMPD, **a single PSMF cannot refer to multiple locations**. Therefore, the same MAH A cannot register different locations for the same PSMF describing the same PV system.

In the case where the MAH changes the location of the PSMF, the maintenance submission applies as described in section [2.3. Maintenance of a Pharmacovigilance System Master File Location \(PSMFL\) entity](#) of this document.

The following case scenarios provide explanations as to when and how an EV Code for a PSMFL needs to be requested by various marketing authorisation holders at different levels (i.e. HQ or affiliates as specified in the EV Registration database):

Table 6 – Requesting a single/multiple PSMFL EV Code(s) by different MAHs

	Scenario 4			Scenario 5		
	4a	4b	4c	5a	5b	5c
MAH	Different	Different	Different	Different	Different	Different
Are MAHs registered in the EV Registration database under the same Global company (HQ)?	Same	Same	Same	Different	Different	Different
Location	Same	Same	Different	Same	Same	Different
PV System	Same	Different	Different	Same	Different	Different
Number of EV Codes to be requested	1	>1	>1	>1	>1	>1
Comment (MF.11) field information	Not required	Not required	Not required	List the EVCODE assigned to the PSMF when it was first registered in the system by the other MAH	Not required	Not required

- Scenario 4a:
 - MAH A and MAH B are **different legal entities** belonging to the **same global company** MAH A and B share the same PV system Y at the **same location** R. Both MAH A and MAH B share the same PSMFL EV Code. I.e.:

MAH A is registered in the EV Registration database as an affiliate of organisation C. MAH B is also registered in the EV Registration database as an affiliate of organisation C. Because both

MAHs share the same PV system at the same location, both should reference the same PSMFL EV Code in their respective AMPs. Since both organisations are affiliates of the same HQ organisation, if MAH A submits a PSMFL entity in the Article 57 database and an EV Code is generated, MAH B will be able to retrieve this PSMFL EV Code in EVWEB.

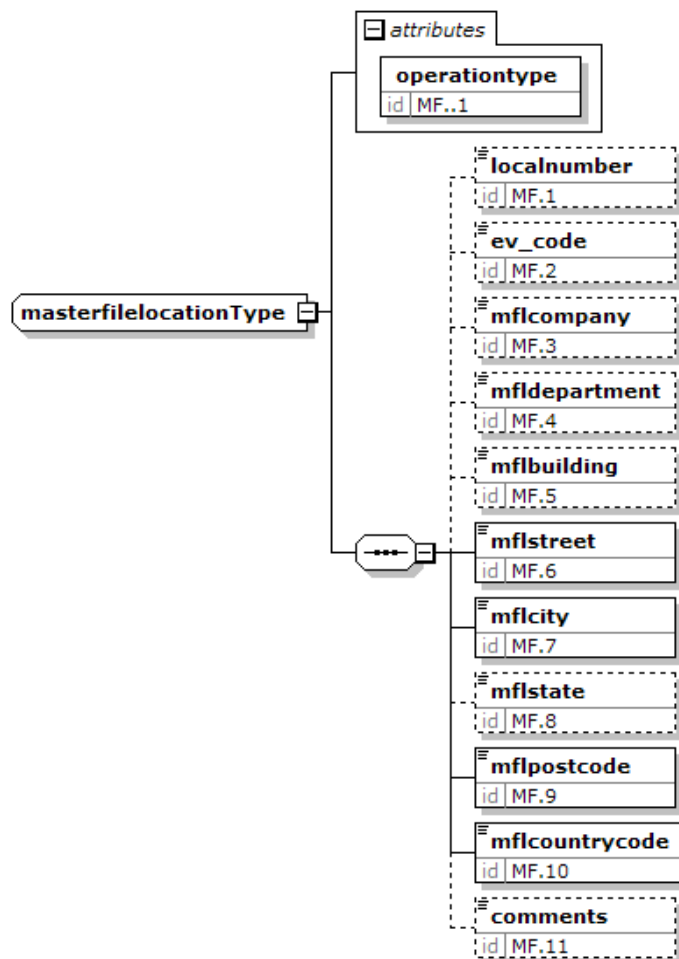
- Scenario 4b:
 - MAH A and MAH B are **different legal entities** belonging to the **same global company**. MAH A and B have **different PV systems** Y and Z at the **same location** R. Therefore, each MAH requests their own individual EV Code, which they will reference in their AMPs.
- Scenario 4c:
 - MAH A and MAH B are **different legal entities** belonging to the **same global company**. MAH A and B have **different PV systems** Y and Z at **different location** R and S. MAH A has a PSMF at location R for one PV system Y; MAH B has a PSMF at location S for one PV system Z. Therefore, each MAH requests their own individual EV Code, which they will reference in their AMPs.
- Scenario 5a:
 - MAH A and MAH B are **different legal entities** belonging to **different global companies**. MAH A and B share the **same PV system** Y at the **same location** R. Both MAH A and MAH B request a separate EV Code. In order to identify that the separate EV Codes refer to the same PV system Y (and corresponding PSMF) describing the same single PV system Y at the same location R, each MAH is required to include in the "Comment" field (MF.11) of the PSMF location entity the EV Code assigned to the other MAH. In case one MAH has already acquired an EV Code, it is acceptable that the other MAHs sharing the same PV system include this PSMFL EV Code in the "Comment" field (MF.11). I.e.:

MAH A is registered in the EV Registration database as a headquarter organisation. MAH B is also registered in the EV Registration database as a headquarter organisation. Since both organisations are separate unrelated organisations, if MAH A submits a PSMFL entity in the Article 57 database and an EV Code is generated, MAH B will NOT be able to retrieve this PSMFL EV Code in EVWEB and reference it in their AMPs. Because both MAHs share the same PV systems at the same location, each MAH should submit a separate PSMFL entity in the Article 57 database, stating the EV Code of the PSMFL submitted by the other MAH in the "Comment" field (MF.11). This means that two PSMFL EV Codes will be generated and each of the MAH will reference a different PSMFL EV Code in their AMPs. The link between the two PSMFL EV Codes will be through the information in the PSMFL "Comment" field (MF.11).
- Scenario 5b:
 - MAH A and MAH B are **different legal entities** belonging to **different global companies**. MAH A and B have **different PV systems** Y and Z at the **same location** R. Therefore, each MAH requests their own individual EV Code, which they will reference in their AMPs.
- Scenario 5c:
 - MAH A and MAH B are **different legal entities** belonging to **different global companies**. MAH A and B have **different PV systems** Y and Z at **different location** R and S. MAH A has a PSMF at location R for one PV system X; MAH B has a PSMF at location S for one PV system Z. Therefore, each MAH requests their own individual EV Code, which they will reference in their AMPs.

See the [Guideline on good pharmacovigilance practices \(GVP\): Module II – Pharmacovigilance system master file \(Rev 2\)](#) for related information.

Organisations registered with Eudravigilance can submit the PSMF location information using the Master File Location section of the XEVPRM (see Table 7. Master File Location elements of Chapter 3.I of the Detailed Guidance for further information) with the operation type 'Insert' (1) in EVWEB or their Gateway.

Master file location element structure:



1.11.1. Local Number (MF.1)

The local number is a unique reference number that must be assigned for an MFL entity in the XEVPRM following an operation type 'Insert' (1).

When an MFL is submitted in an XEVPRM using the operation 'Insert' (1), a local number must be assigned to this MFL entity. When the corresponding XEVPRM Acknowledgement is received and providing that the submission was successful, this local number should be used to identify the corresponding EV Code.

EXAMPLE: XEVPRM – Insert of MFL information

```
- <masterfilelocation operationtype="1">  
  <localnumber>1</localnumber>  
  <mflstreet>Example street</mflstreet>  
  <mflcity>London</mflcity>  
  <mflpostcode>E14 4HB</mflpostcode>  
  <mflcountrycode>GB</mflcountrycode>
```

EXAMPLE: XEVPRM Acknowledgement – Insert of MFL

```
- <reportacknowledgment>  
  <reportname>MFL</reportname>  
  <localnumber />1</localnumber>  
  <ev_code>MFL12345</ev_code>  
  <operationtype>1</operationtype>  
  <operationresult>2</operationresult>  
  <operationresultdesc>Entity inserted successfully</operationresultdesc>  
</reportacknowledgment>  
</acknowledgment>  
</evprmack>
```

1.11.2. EV Code (MF.2)

EudraVigilance (EV) Code of the MFL must be specified if the operation type is NOT an 'Insert'.

I.e. if maintenance related operations are performed on a MFL entity successfully inserted in the XEVMPD, the EV Code of the MFL entity must be referenced in this field.

1.11.3. Pharmacovigilance System Master File Company (MF.3)

The name of the company that holds the PSMF may be specified where applicable.

1.11.4. Pharmacovigilance System Master File Department (MF.4)

The name of the department that holds the PSMF may be specified where applicable.

1.11.5. Pharmacovigilance System Master File Building (MF.5)

The building name, if part of the address may be specified where applicable.

1.11.6. Pharmacovigilance System Master File Street (MF.6)

The street of the address where the master file is located must be specified.

1.11.7. Pharmacovigilance System Master File City (MF.7)

The city of the address where the master file is located must be specified.

1.11.8. Pharmacovigilance System Master File State (MF.8)

The state/region of the address where the master file is located may be specified.

1.11.9. Pharmacovigilance System Master File Postcode (MF.9)

The postcode of the address where the master file is located must be specified.

1.11.10. Pharmacovigilance System Master File Country code (MF.10)

The country code of the address where the master file is located must be specified.

1.11.11. Comment (MF.11)

Internal reference to distinguish which PSMF is related to the specific PSMF Location EV Code may be included as outlined in table scenario 5a.

When operation type 'Nullification' (4) is performed on MFL entity, the comment field must be populated with the reason for nullification (e.g. "Duplicate of XXX"). Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform the nullification.

Following a successful insert, an EV Code for the MFL entity will be received in the XEVPRM Acknowledgement. The pattern of the EV Code for a master file location is 'MFL' followed by a number.

2. Maintenance of medicinal product data

Scope and objectives

This chapter defines the maintenance of information of medicinal products submitted by marketing authorisation holders in accordance with the provisions laid down in Article 57(2) of Regulation 726/2004.

From 16 June 2014 until ISO IDMP implementation, marketing authorisation holders are required to amend the authorised medicinal product entities submitted in the XEVPRM format in compliance with the requirements of Article 57(2) of Regulation (EC) 726/2004. The guidance and processes described in this chapter should be followed during the 'transition maintenance phase' [i.e. the transition to the ISO Identification of Medicinal Product (IDMP) standards implementation].

A long-term strategy for the implementation of the ISO IDMP standards is currently being developed by the Agency, taking into account the potential impact on the European Regulatory Network, EU stakeholders and international partners. Information related to the implementation of ISO IDMP standards in the European Union can be found on the [Implementation of the ISO IDMP standards webpage](#).

The scope of the 'transition maintenance phase' submission is:

- to collect up-to-date information on authorised medicinal products initially submitted under the Article 57(2) requirements in the XEVMPD by correcting any erroneously submitted information;
 - for Gateway user this includes the reconciliation of the medicinal product data against the new EV Code provided in the XEVMPD CVs following the quality control activities performed by the Agency (i.e. XEVMPD substance names, pharmaceutical forms and routes of administration CVs),
- to reflect any changes to the terms of the marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal of the marketing authorisation procedure within the XEVMPD/Article 57 database structured and non-structured information as per timelines set in the Legal Notice (within 30 calendar days from the date of which the amendments have been authorised);
- to continue the submission of new authorised medicinal products in the XEVMPD as per timelines set in the Legal Notice (within 15 calendar days from the date of authorisation).

The 'transition maintenance phase' as described in this guidance document enables the Agency to establish a complete and reliable database on medicinal product information to support the following areas:

- performance of data analysis at the Agency and specifically:
 - EudraVigilance (EV) data analysis and signal management,
 - coding and providing of reporting possibilities on medicinal product and substance information within Individual Case Safety Reports (ICSRs),
 - to support data analytics and business intelligence activities;
- facilitate medicines regulation and fulfil regulatory actions and legal obligation such as:

- regulatory action to safeguard public health (e.g. referrals, PSUR repository, literature monitoring),
- calculation of Pharmacovigilance fee;
- communicate efficiently with EMA stakeholders by means of:
 - establishing a European medicines web portal,
 - granting access to EudraVigilance data proactively and reactively,
 - supporting EU and international data exchange on demand,
 - supporting the Pharmacovigilance Risk Assessment Committee (PRAC) for any communication with its stakeholders.

Transition maintenance phase - Electronic submission plan

Between 16 June 2014 and 31 December 2014 at the latest, marketing authorisation holders were required to:

- update, complete and improve the quality of medicinal products submitted in the context of Art 57(2) of Regulation (EC) No 726/2004; and
- provide to the Agency additional information on all medicinal products submitted under Article 57(2) provisions and in compliance with the new XEVPRM format as published by the Agency on 31st January 2014.

As of 1 January 2015 marketing authorisation holders are required to notify to the Agency any subsequent changes to the terms of marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal of the marketing authorisation as soon as possible and no later than **30 calendar days** from the date of which the changes have been authorised using the electronic XEVPRM format as amended on 31 January 2014.

Marketing authorisation holders should notify the Agency about **amendments to the terms of marketing authorisations** which require a revision of the information on medicinal products as referred to in paragraph 3 and 4 of the Legal Notice and the applicable structured data elements (mandatory/mandatory with conditions) of the electronic XEVPRM format as amended by the Agency on 31 January 2014. More specifically, notifications of the amendments to the terms of the marketing authorisation include:

- notification of extensions of marketing authorisations as defined in paragraph 1 and 2 of Annex I of Regulation (EC) 1234/2008: changes to the active substance(s), strength, pharmaceutical form and route of administration;
- notification of variations to the terms of marketing authorisations as set out in Regulation (EC) 1234/2008 that is affecting the following XEVPRM structured data elements (mandatory/mandatory with conditions):
 - SmPC Section 1. Name of the medicinal product e.g. change in the (invented) name of the medicinal product,
 - SmPC Section 2. Qualitative and quantitative composition e.g.: changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza,

- SmPC Section 3. Pharmaceutical Form e.g. change(s) to a pharmaceutical form, which does not result in a "new pharmaceutical form" (the latter requires the submission of an Extension application),
 - SmPC Section 4.1 Therapeutic indications e.g. addition of a new therapeutic indication or modification of an existing one,
 - SmPC Section 4.2 Posology and method of administration (routes of administration only) e.g. change(s) to route(s) of administration,
 - SmPC Section 5.1 Pharmacodynamic properties e.g. change in ATC code,
 - SmPC Section 6.1 List of excipients e.g. change or addition of excipient(s),
 - SmPC Section 7. Marketing Authorisation Holder *e.g. a change of name and/or address of the MAH;*
- notification of any changes to the name and the contact details of the qualified person responsible for pharmacovigilance (QPPV) in accordance with Article 4(4) of Commission Implementing Regulation (EU) no 520/2012;
 - notification of any changes in the location of the Pharmacovigilance system master file (PSMF);
 - notification of any changes to the contact information for Pharmacovigilance enquiries;
 - notifications of transfers of marketing authorisations;
 - notifications of any suspension/lifting of the suspension, revocation or withdrawal of a marketing authorisation granted in the Union;
 - notifications of any suspension/lifting of the suspension, revocation or withdrawal of a marketing authorisation granted in the Union including the following circumstances:
 - the marketing authorisation was not renewed by the relevant competent authority,
 - an application was not submitted for renewal by the marketing authorisation holder, or
 - the marketing authorisation expired due to sunset clause;
 - notifications of renewal of the marketing authorisation;
 - notification of the electronic copy of the latest approved Summary of Product Characteristics (SmPC) where any variations lead to a significant revision of the content of the following sections:
 - section 4.1 Therapeutic indications which do not have a direct impact on the MedDRA coding of the indication,
 - section 4.2 Posology and method of administration (other than route of administration),
 - section 4.3 Contraindications,
 - section 4.4 Special warnings and precautions for use,
 - section 4.5 Interaction with other medicinal products and other forms of interaction,
 - section 4.6 Fertility, Pregnancy and lactation,
 - section 4.8 Undesirable effects,
 - section 4.9 Overdose.

2.1. Maintenance of a Qualified Person responsible for Pharmacovigilance (QPPV)

MAHs are legally required to have a qualified person for pharmacovigilance (QPPV) based in the European Union (EU) in place at all times, in line with Directive 2001/83/EC Article 104(3)(a).

The QPPV must be registered in Eudravigilance.

MAH organisations with QPPVs residing in the UK and/or carrying their tasks in the UK should also note Q&A 4. of the ['Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure'](#) document for related information.

The contact details of the Qualified Person responsible for Pharmacovigilance (QPPV) refer to the contact details from where the QPPV operates.

From 1 February 2016 MAH organisations no longer need to notify the EMA or the national competent authorities (as applicable) of changes to the QPPV by submitting a type IA_{IN} variation. From this date, the Article 57 database is considered functional for the purpose of notifying changes in QPPV including contact details (telephone and fax numbers, postal address and email address) through the Article 57 database only. No final variation is required to notify an explicit cross reference to Article 57 as the source of QPPV information.

Changes to the QPPV information must be notified in the affected medicinal product entities in the Article 57 database using one of the below business processes (as applicable) immediately and no later than **30 calendar days** from the date the change applies:

1. business process to notify the change of the QPPV details (same person) e.g. changes of telephone number/address or surname;
2. business process to notify the change of the QPPV within the organisation (change of person) e.g. QPPV retires, new QPPV is appointed.

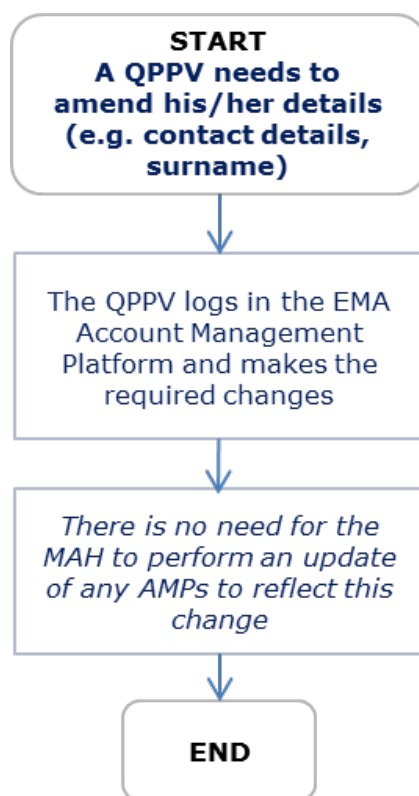
2.1.1.1. Business process to notify the change of QPPV's details

From 26 July 2018 the QPPV/RP is required to make any changes of the QPPV's details (e.g. change of telephone number/address or surname) in his/her profile via the [EMA Account Management Platform](#). Please refer to the [EMA EudraVigilance Registration Manual](#) for related information.

The change of QPPV's details does not affect any medicinal product entries referencing the QPPV as the same QPPV Code continues to be referenced in the relevant AMP and there is therefore no need for the MAH to perform an update of the AMP entities.

The following business process should be followed to notify a change to the QPPV's details (same person):

Process map 3 – Change of QPPV's details



2.1.1.2. Business process to notify a change of a QPPV

From 26 July 2018, when a new QPPV is appointed in an MAH organisation, the organisation must nominate a new QPPV within 10 calendar days; the new QPPV must self-register for the relevant QPPV role (i.e. either as the 'EU QPPV' (at a HQ level) or as an 'additional QPPV' (at an affiliate level) via the [EMA Account Management Platform](#).

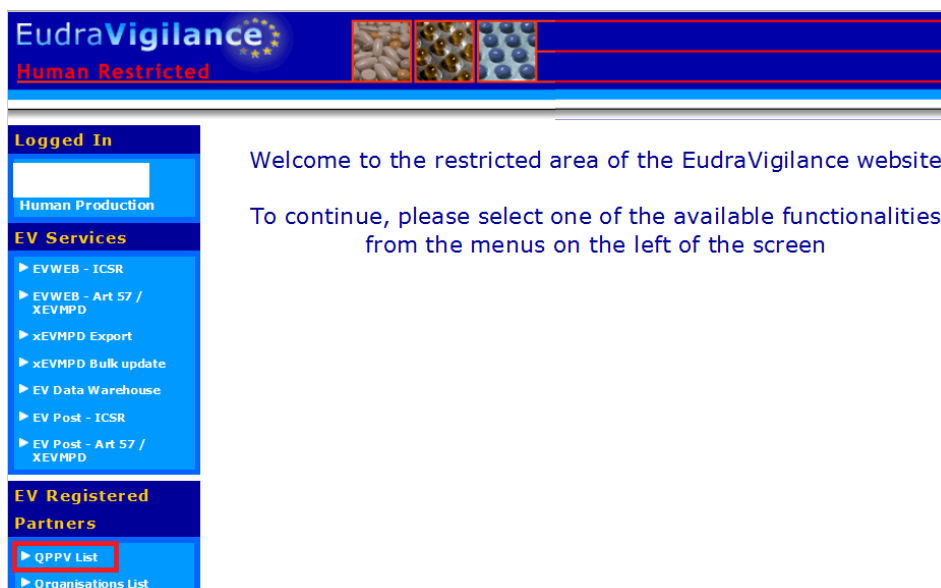
There can only be one EU QPPV per HQ organisation. The existing EU QPPV/RP cannot be removed from EudraVigilance until their replacement is fully registered in the EMA Account Management Platform.

- The registration of an 'EU QPPV' (at a HQ level) via the [EMA Account Management Platform](#) is approved by the EMA following the receipt of a request submitted via the [EMA Service Desk](#). A set of documents must be submitted with the request as indicated in the document [Change of qualified person for pharmacovigilance and responsible person for EudraVigilance](#).
- The registration of an 'additional QPPV' (at an affiliate level) and/or the trusted deputy is approved by the EU QPPV of the MAH organisation.
- When a new QPPV is appointed at an EU level (i.e. for the MAH HQ organisation) the QPPV that is no longer valid will need to de-register from the EU QPPV role via the [EMA Account Management Platform](#) and a new QPPV will need to request a registration for this role.

For information on how to register, refer to the published [EMA EudraVigilance Registration Manual](#).

Following the registration of the new QPPV a new QPPV Code is assigned. The MAH can retrieve this QPPV Code from:

- the EudraVigilance website (restricted area accessible for registered users only) under "QPPV list" (by Gateway/EVWEB users):



- or via the EudraVigilance look-up table in the XEVMPD Data Entry Tool (EVWEB) (by EVWEB users).

The MAH should amend any affected AMPs with a valid marketing authorisation status in the XEVMPD using an operation type 'Update' (2) accordingly.

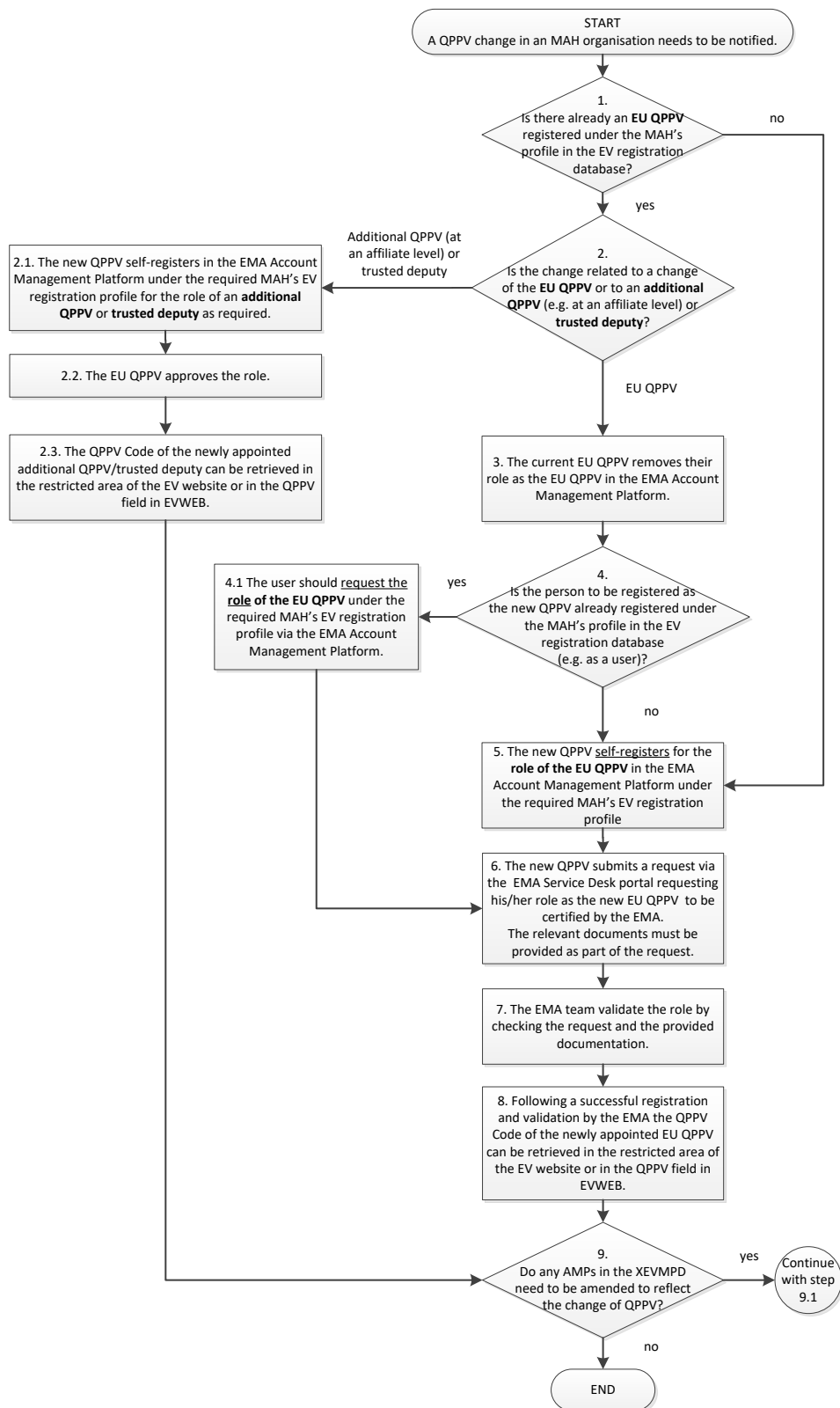
In cases when the marketing authorisation of a medicinal product is transferred to a new MAH but the QPPV remains the same, he or she must be registered (via the [EMA Account Management Platform](#)) under the EV profile of the new MAH. This is because the QPPV is linked to the organisation profile under which he or she is registered in the EV registration database. It is not technically possible to reference a QPPV registered under a profile of another organisation unless there is an affiliate and HQ relationship between both organisations.

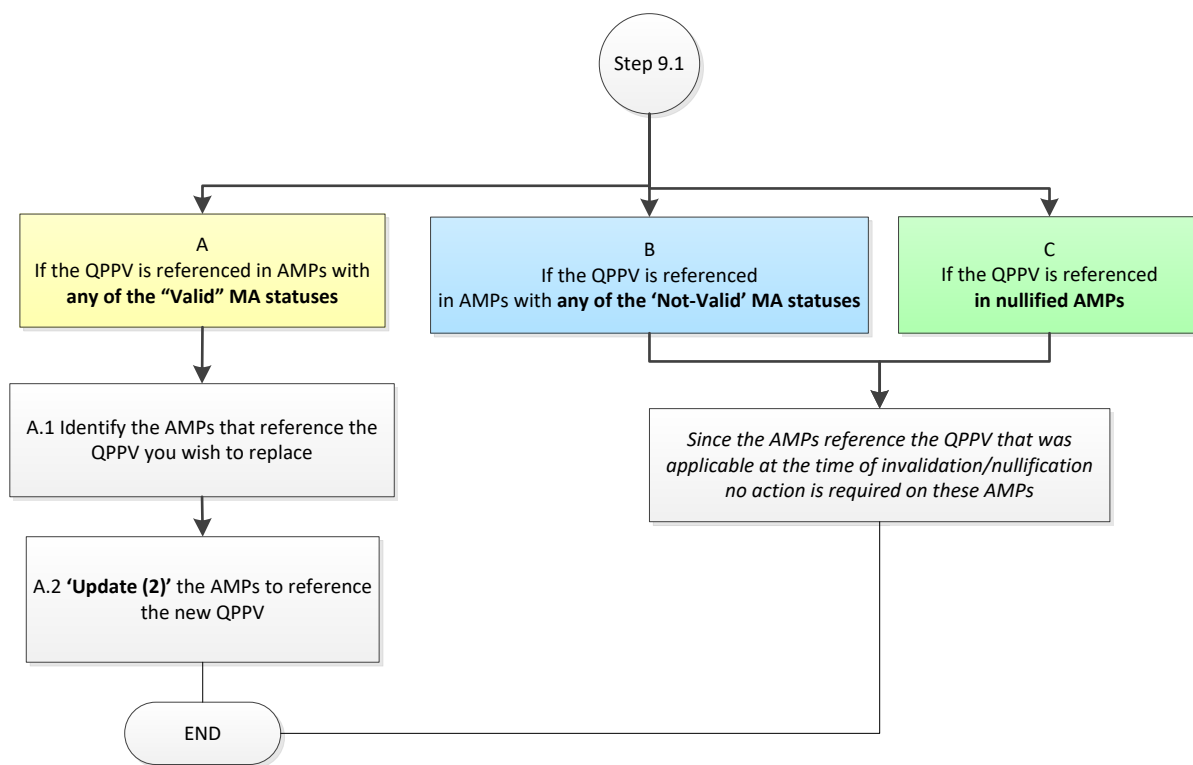
Therefore, to be referenced in the AMPs submitted from the organisation ID of the new MAH, the QPPV of the former MAH must be registered as a QPPV (or a deputy QPPV or additional QPPV) of the new MAH. This can be arranged by the QPPV by self-registering under the required organisation profile (e.g. as an 'additional QPPV') in the [EMA Account Management Platform](#).

Example: Product A was transferred from MAH A to MAH B. Both MAH organisations are registered in EV as two separate HQ organisations. The QPPV of MAH A remains the QPPV of Product A for a certain period. Therefore, for the QPPV of MAH A to be referenced in the product submitted from MAH B's profile, the QPPV must be registered under the EV profile of MAH B (new QPPV Code will be assigned).

The following business process should be followed to notify a change of QPPV (different person) within the organisation:

Process map 4 – Change of a QPPV





2.2. Maintenance of a marketing authorisation holder (MAH) organisation entity

Variations to the information of the marketing authorisation holder (MAH) may trigger one of the following business processes:

- **Notification of change of contact details, name and/or address of the MAH (i.e. no change of the legal entity)**

Change of contact details, name and/or address of an MAH, if the organisation remains the same legal entity, should be reflected by performing an '**Update (2)**' on the existing MAH organisation entity (i.e. an EV Code is already assigned) or an '**Insert (1)**' of a new MAH entity (new EV Code will be assigned).

If an update of information is performed on an existing MAH entity, then all AMP entities referencing that MAH organisation entity will display the updated MAH information.

If the name and/or address of the MAH are not yet updated in section 7. of the SmPC(s) for the AMP(s) with any of the 'Valid' marketing authorisation statuses in the XEVMPD:

- The AMPs referencing SmPCs that do not yet contain the new details of the MAH should continue to reference the existing MAH entity (i.e. with the old details).
- A new MAH entity with the updated details should be entered in the XEVMPD using operation type 'Insert (1)'. New organisation EV Code will be assigned.
- The AMPs referencing SmPCs that already contain the new details of the MAH should be updated [operation type 'Update (2)'] to reference this new MAH entity.

Update of the organisation EV Code in the XEVMPD will not trigger the update of your organisation's details in the EudraVigilance Registration database. To amend details of your organisation in the list of organisations registered with EudraVigilance in the restricted area of the EudraVigilance Human website please raise a **change request** in the [Organisations Management system \(OMS\) available at the SPOR portal](#). Further information on how to amend organisation details in OMS can be found in the OMS web user manual available in the 'Help' section of the *OMS portal*, in section [8.2. Change request process – general rules](#).

- **Notification of transfer of marketing authorisation (i.e. change of the legal entity)**

The business process to notify the transfer of marketing authorisation (i.e. change of the Legal entity) is described in section [2.4.3. Transfer of marketing authorisation](#) of this document.

MAHs are required to correct and reconcile MAH organisation details using an XEVPRM with the assigned operation types 'Insert' (1), 'Update' (2) and 'Nullification' (4) as described below.

Only the owner organisation (i.e. the organisation that submitted the data and/or its HQ) can perform maintenance related operation types 'Update' (2) and 'Nullification' (4) on an MAH entity in the XEVMPD.

When a new MAH organisation information (new MAH EV Code) is required, the operation type '**Insert (1)**' must be used to submit a new MAH organisation entity in the XEVMPD in an XEVPRM; a new MAH EV Code will be assigned. This newly submitted organisation should then be referenced in AMPs with any of the 'Valid' MA statuses for which the attachments reference the updated organisation details (e.g. in section 7 of the SmPC). See section [1.6. Initial submission of a marketing authorisation holder \(MAH\) organisation](#) of this document for related information.

Amendment of information within an existing organisation entity should be performed by submitting an XEVPRM with operation type '**Update (2)**' on the existing MAH entity. All AMP entities referencing the MAH organisation entity, for which the details were amended, will automatically reference the amended/added information.

MAH organisation entity, which is duplicated (i.e. multiple EV Codes are assigned to the same organisation entity), obsolete (the organisation is not/will not be referenced in any product submissions) or erroneously submitted can be either:

- nullified by submitting an XEVPRM with operation type '**Nullification (4)**'; the text "*Obsolete entity*" or "*Duplicate of ORGXXX*" (where ORGXXX represents an EV Code) should be entered in the 'Comment (O.18)' field; or
- flagged as 'non-current' by submitting an XEVPRM with operation type '**Update (2)**' and referencing the text "*Obsolete entity*" or "*Duplicate of ORGXXX*" (where ORGXXX represents an EV Code) in the 'Comment (O.18)' field.

The applicable operation type (i.e. update/nullification) should be applied to the MAH organisation entity depending on the type of medicinal product entities in which this MAH entity is referenced. The following must be taken into consideration:

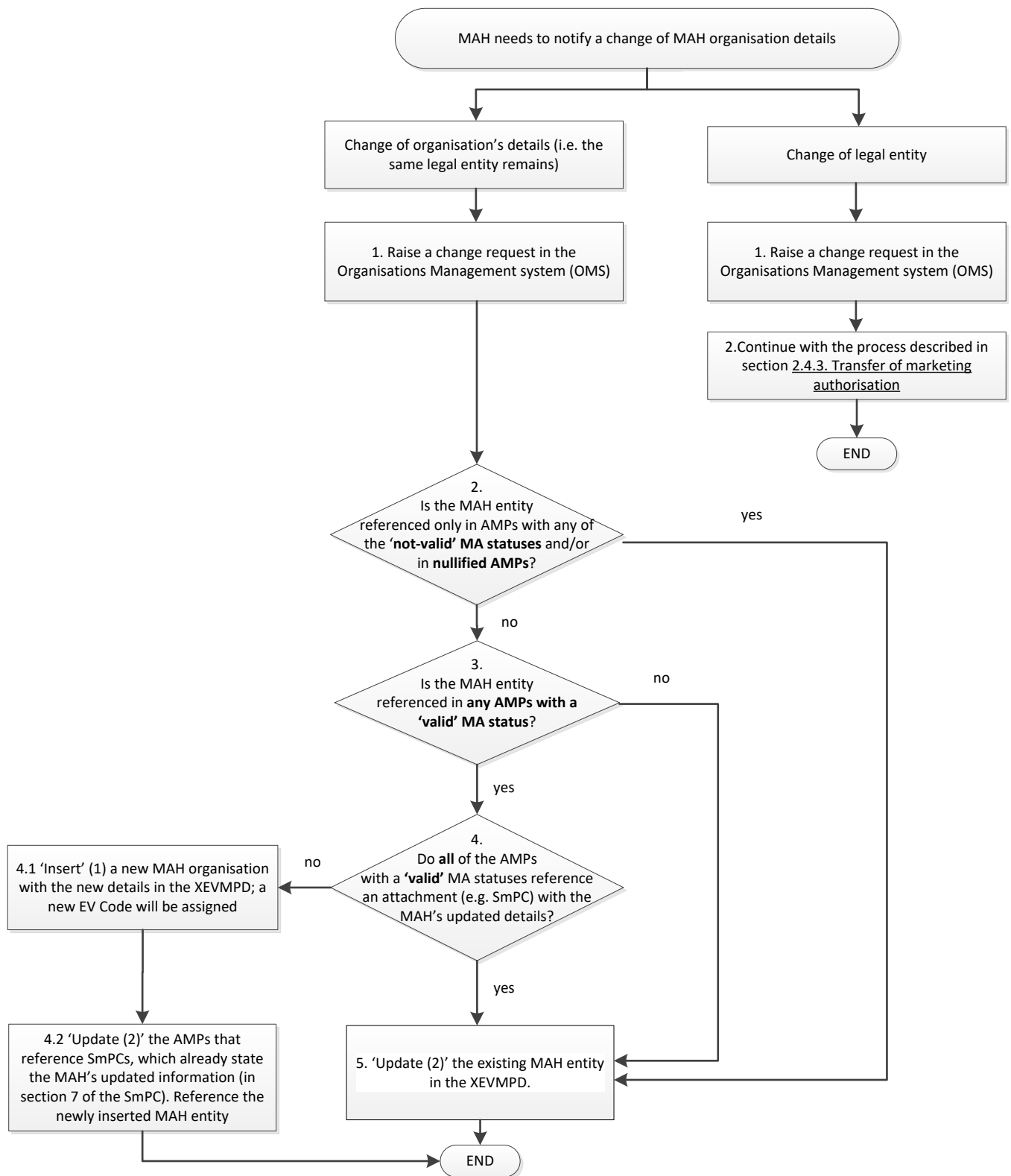
- a) Nullification of a duplicated/obsolete MAH entity can only be performed if the MAH entity is referenced **only in nullified AMPs**; the text "*Obsolete entity*" or "*Duplicate of ORGXXX*" (where ORGXXX represents an EV Code) should be entered in the 'Comment (O.18)' field.
- b) Nullification is not allowed on MAH organisation entities validated (i.e. the 'Validity' field displays 'Valid') by the EMA in the XEVMPD; only the EMA can nullify such MAH organisation entities providing they are referenced only in nullified AMPs. MAH should submit a nullification request using the EMA Service Desk portal (<https://servicedesk.ema.europa.eu>). The EV Code of the MAH organisation entity, the requestor's organisation name and EudraVigilance registration ID, and the reason for nullification must be included in the request.
- c) If the duplicated/obsolete MAH entity is referenced in AMPs with **any of the 'Valid' marketing authorisation statuses** the AMPs should be updated [i.e. operation type 'Update (2)'] to reference another MAH entity, which will be retained in the XEVMPD.
- d) If the duplicated/obsolete MAH entity to be flagged as 'non-current' is referenced in AMPs with **any of the 'Not-Valid' marketing authorisation statuses** the duplicated/obsolete MAH entity should be updated [i.e. operation type 'Update (2)'] to reference the text "*Obsolete entity*" or "*Duplicate of ORGXXX*" (where ORGXXX represents an EV Code) in the 'Comment (O.18)' field.

Following the submission of an XEVPRM in the XEVMPD, the MAH should refer to the XEVPRM Acknowledgment to check if the performed action has been successful.

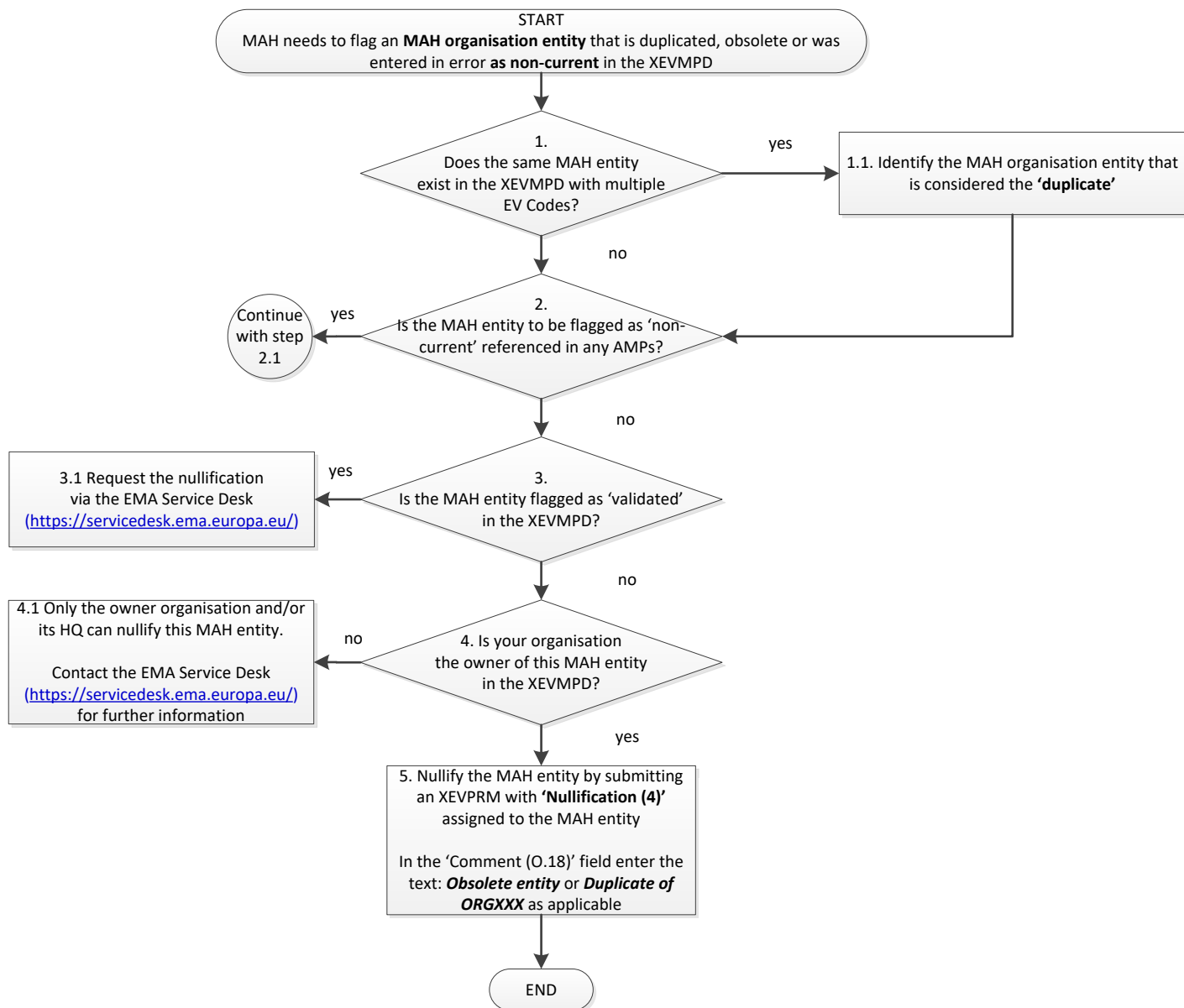
The below business processes describe how to:

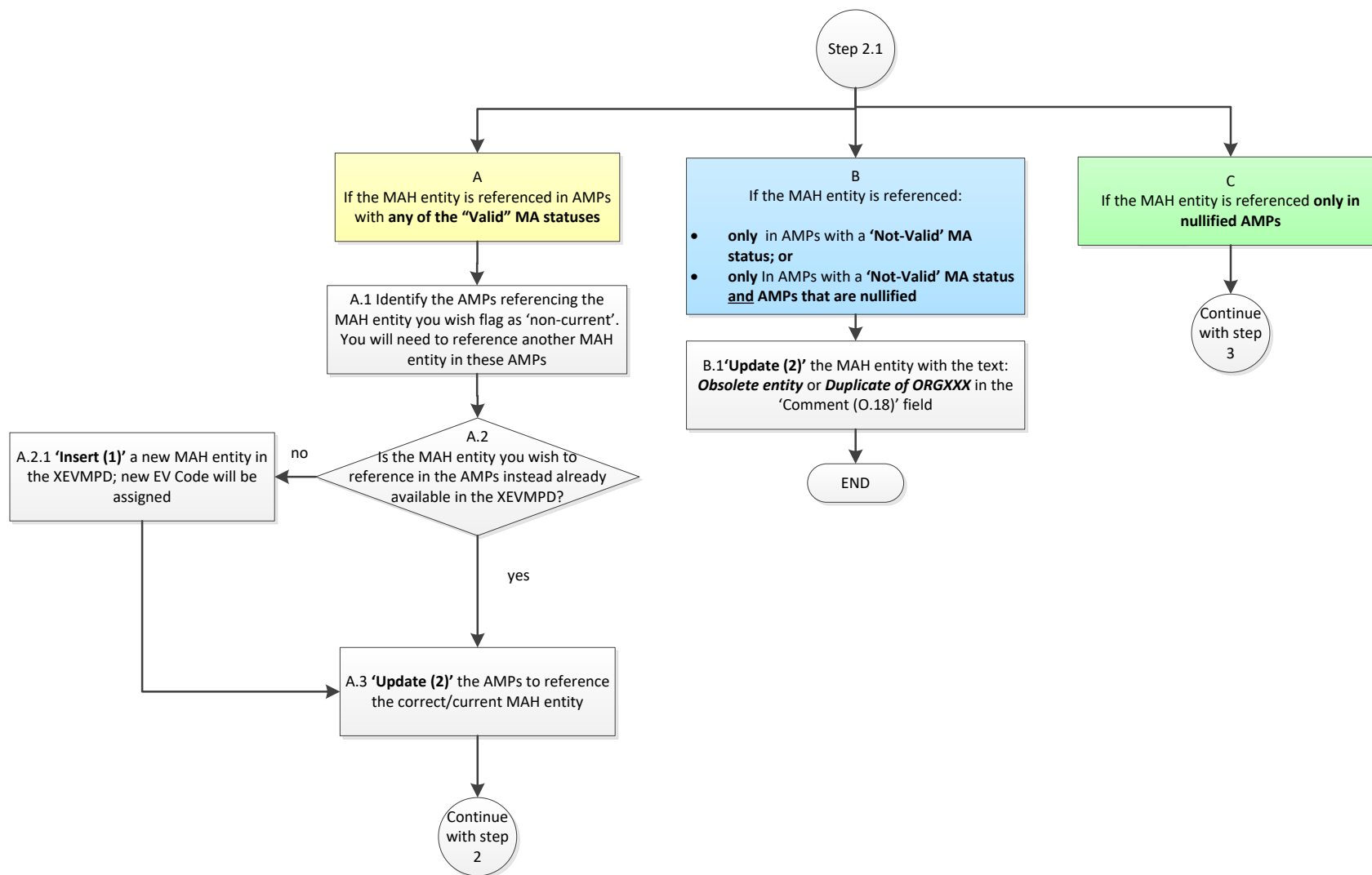
- notify changes to the MAH details (same organisation/legal entity);
- notify an MAH entity as 'non-current'.

Process maps 5 – Change of MAH details



Process map 6 – Notifying an MAH entity as 'non-current'





2.3. Maintenance of a Pharmacovigilance System Master File Location (PSMFL) entity

As per information in the [Guideline on good pharmacovigilance practices \(GVP\): Module II – Pharmacovigilance system master file](#):

- Marketing authorisation holders shall continue to ensure that their entries in the Article 57 database for medicinal products for human use are up-to-date, including the information about the qualified person responsible for pharmacovigilance (QPPV), name and contact details (telephone and fax numbers, postal address and email addresses) and PSMF location information [based on IR Art 4(4)].

Upon a change in the QPPV or location of the PSMF information, the Article 57 database shall be updated by the marketing authorisation holder immediately and no later than 30 calendar days, in order to have the information in the Article 57 database and on the European medicines web-portal referred to in Article 26(1) of Regulation (EC) No 726/2004 updated and to allow continuous supervision by the competent authorities [based on IR Art 4(4), REG Art 57(2)(c)].

Changes to the information on the Pharmacovigilance system may trigger the generation of new PSMFL EV Code(s) in the Article 57 database. Please refer to the guidance provided in [Table 5 – Requesting a single/multiple PSMF EV Code\(s\) by the same MAH](#) and [Table 6 – Requesting a single/multiple PSMFL EV Code\(s\) by different MAHs](#).

MAH organisations with Pharmacovigilance System Master File located in the UK should also note Q&A 5. of the ['Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure'](#) document for related information.

In accordance with Article 3 of Regulation (EU) NO 1235/2010 (the pharmacovigilance legislation), the obligation on the part of the MAHs to maintain and make available on request a Pharmacovigilance System Master File (PSMF) will apply "... to marketing authorisations granted before 2 July 2012 as from either:

(a) the date on which those marketing authorisations are renewed; or

(b) the expiry of a period of 3 years starting from 2 July 2012,

whichever is the earlier.

Therefore from 2 July 2015 MAHs are required to submit the Pharmacovigilance system information to the Article 57 database.

From 1 February 2016 MAH organisations no longer need to notify EMA or national competent authorities (as applicable) of changes to the pharmacovigilance system data by submitting a type IAIN variation. From this date Article 57 database is considered functional for the purpose of notifying changes to the location of the PSMF (street, city, postcode, country) through the Article 57 database only. No final variation is required to notify an explicit cross reference to Article 57 as the source of PSMF information.

MAHs are required to correct and reconcile the pharmacovigilance system information by using the operation types 'Insert' (1), 'Update' (2) and 'Nullification' (4) on a PSMFL entity in the Article 57 database as follow:

- When a new pharmacovigilance system code is required, the operation type **'Insert' (1)** must be used to submit the new PSMFL entity in the XEVMPD in an XEVPRM.

- Information within a previously submitted PSMFL entity must be amended or additional information must be added (as applicable) by submitting an XEVPRM with the operation type '**Update**' (2) on an existing PSMFL entity. All AMP entities referencing the PSMFL entity for which the details were amended will automatically reference the amended/added information.

Should the **location** of the PSMF change but the Pharmacovigilance System remains the same, the **existing PSMFL EV Code** should be amended using an operation type '**Update**' (2) to reference the new location.

A new PSMFL entity should be submitted in the Article 57 database only in case where the Pharmacovigilance System changes; a **new PSMFL EV Code** will be generated.

- PSMFL entity which is duplicated (i.e. multiple EV Codes are assigned to the same PSMFL entity), obsolete (the PSMFL is not/will not be referenced in any product submissions) or erroneously submitted (e.g. the entity was not supposed to be submitted) can be flagged as 'non-current' by submitting an XEVPRM with the operation type '**Nullification**' (4) or '**Update**' (2), as applicable.

The applicable operation type (i.e. update/nullification) should be performed on the PSMFL entity depending on the type of medicinal product entities in which the PSMFL entity is referenced. The following must be taken into consideration:

- The duplicated/obsolete PSMFL can only be nullified if the PSMFL entity is referenced **only in nullified AMPs**; the text "*Obsolete entity*" or "*Duplicate of MFLXXX*" (where MFLXXX represents an EV Code) should be entered in the 'Comment (MF.11)' field of the PSMFL entity.
- If the duplicated/obsolete PSMFL entity is referenced in AMPs with **any of the 'Valid' marketing authorisation statuses**:
 - a) the AMPs should be updated [i.e. operation type 'Update (2)'] to reference another PSMFL entity, which will be retained in the XEVMPD; and
 - b) the duplicated/obsolete PSMFL entity should be updated [i.e. operation type 'Update (2)'] to reference the text "*Obsolete entity*" or "*Duplicate of MFLXXX*" in the 'City (MF.7)' field of the PSMFL entity.

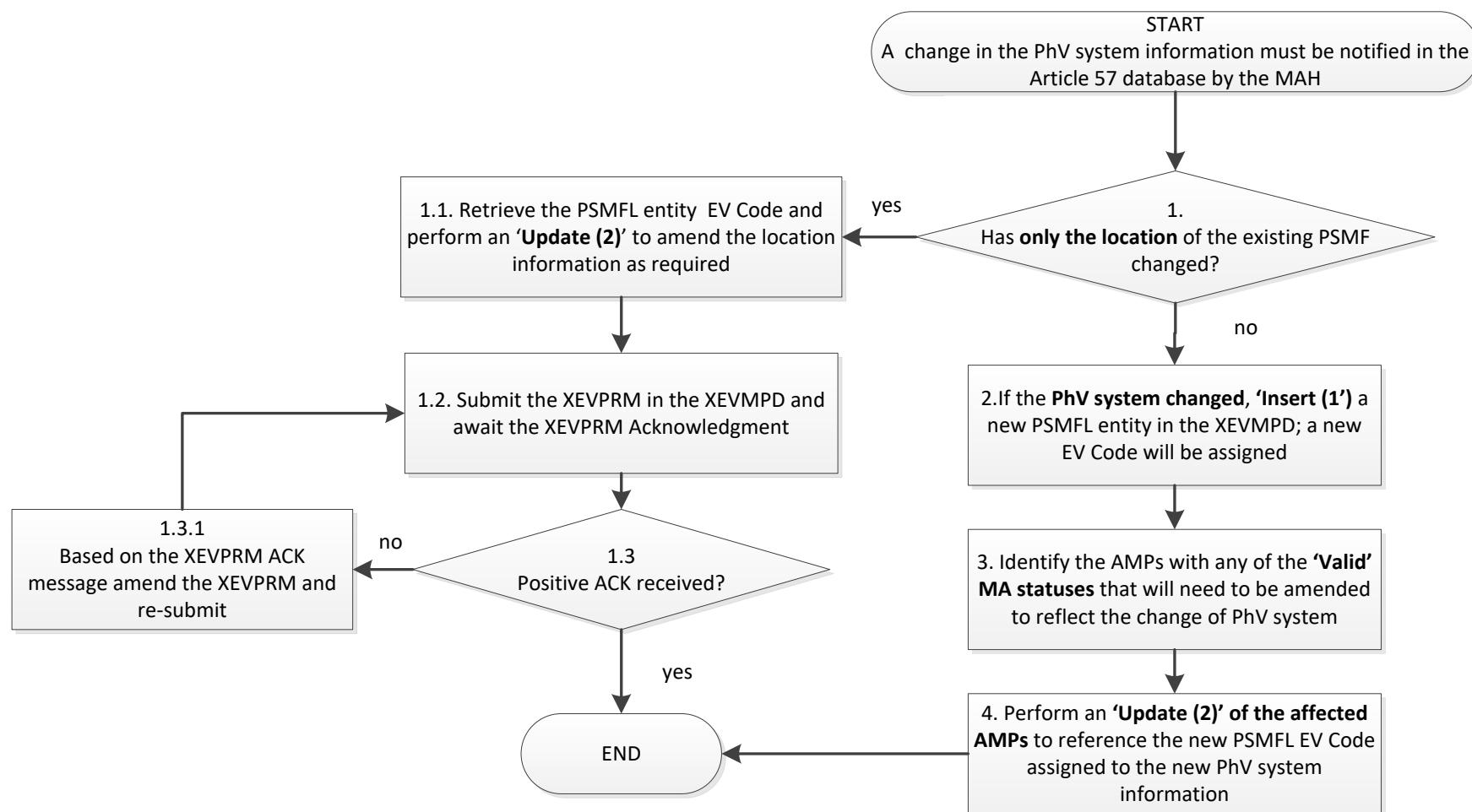
EXAMPLE: "*Prague – Obsolete entity*", "*Rochester – Duplicate of MFL0001*"
- If the duplicated/obsolete PSMFL is referenced in AMPs with **any of the 'Not-Valid' marketing authorisation statuses and nullified AMPs** the PSMFL should be updated [i.e. operation type 'Update (2)'] to reference the text "*Obsolete entity*" or "*Duplicate of MFLXXX*" in the 'City (MF.7)' field of the PSMFL entity.

Following the submission of an XEVPRM in the XEVMPD, the MAH should refer to the XEVPRM Acknowledgment to check if the performed action has been successful.

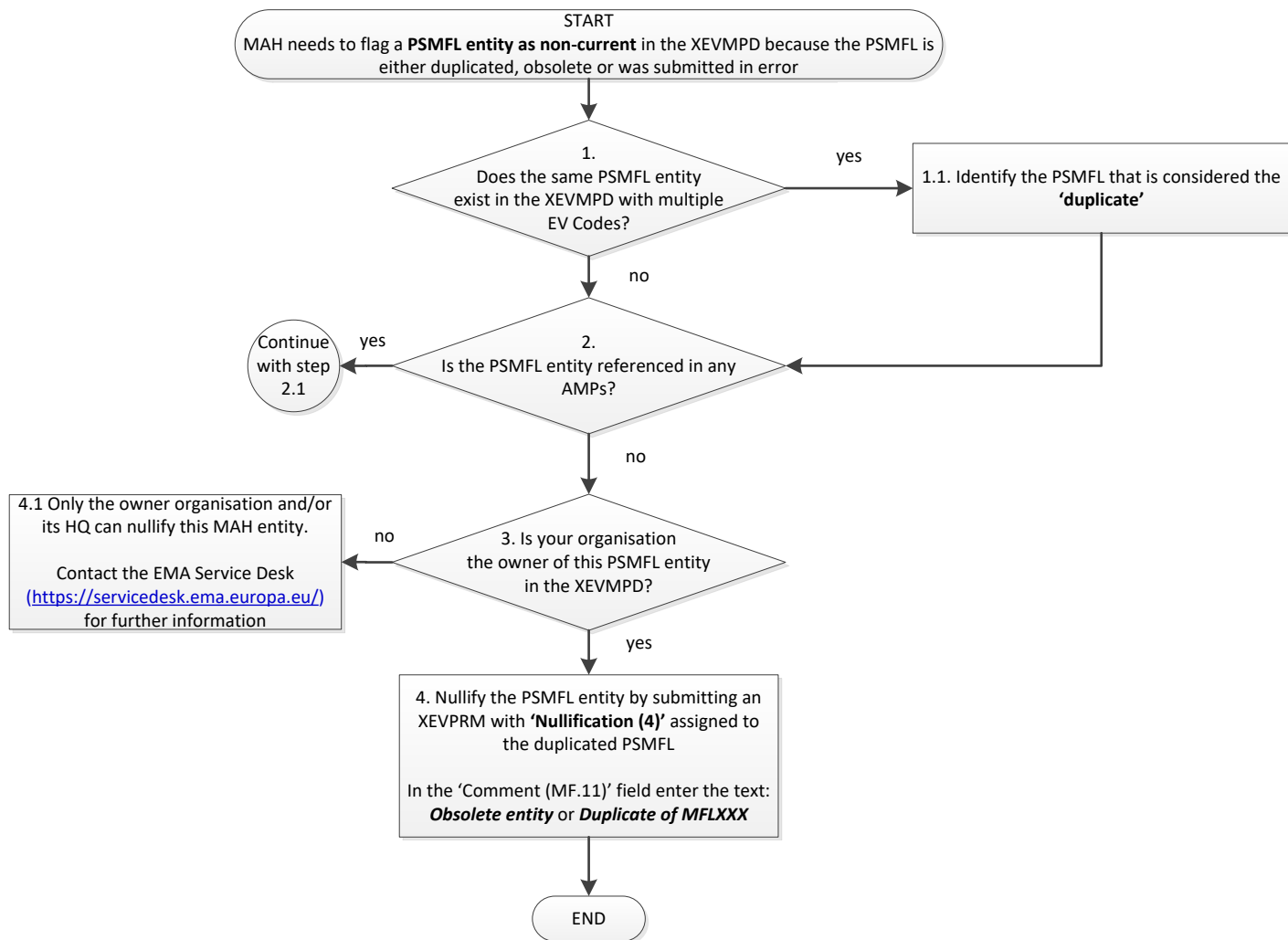
The below business processes describe how to:

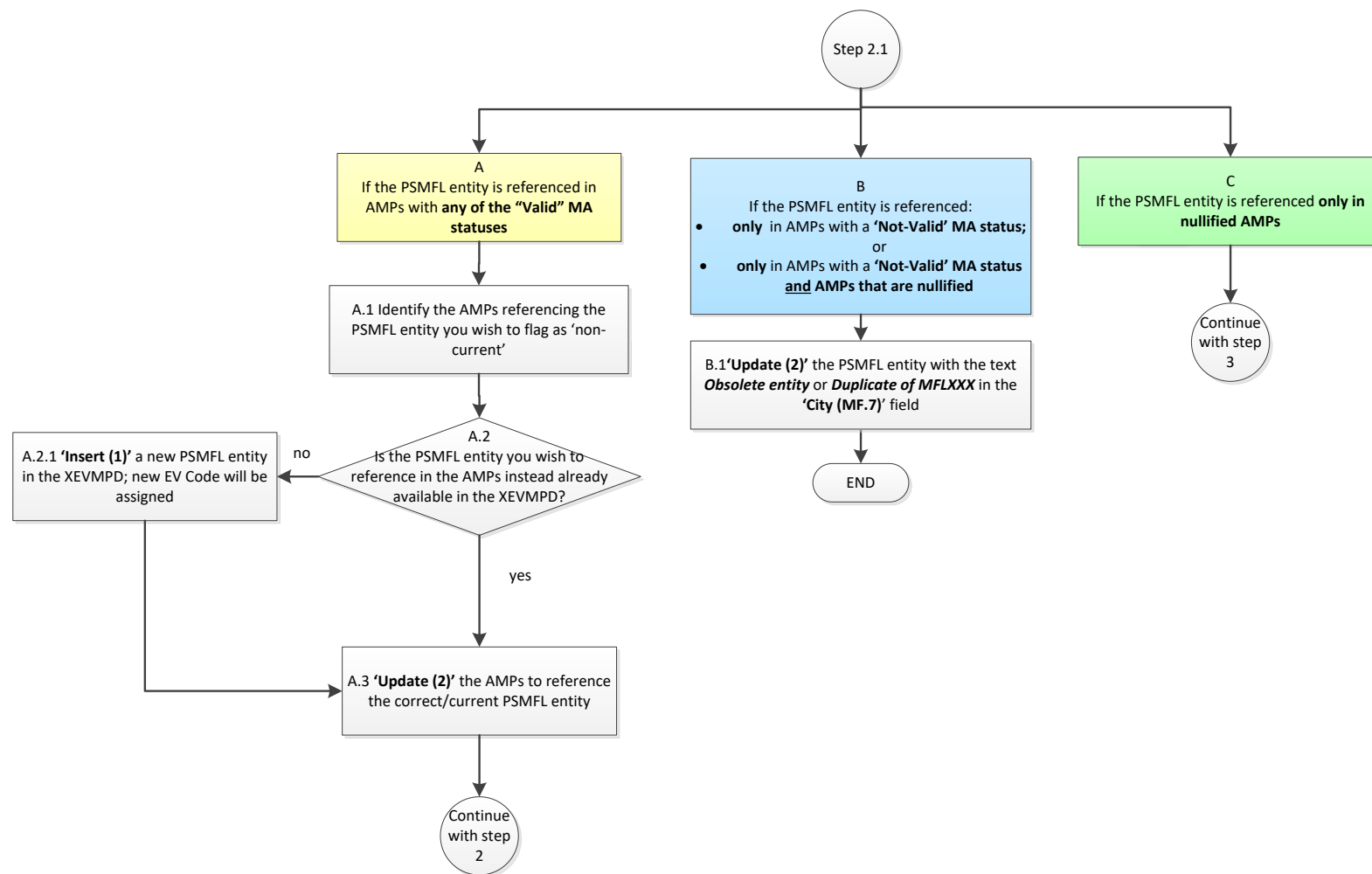
- notify changes to the pharmacovigilance system information;
- notify a PSMFL entity as 'non-current'.

Process map 7 – Change of PSMF information



Process map 8 – Notifying a PSMFL entity as 'non-current'





2.4. Maintenance of an authorised medicinal product (AMP) entity

Marketing authorisation holders should notify the Agency about changes to the terms of marketing authorisations, which require a revision information on medicinal products and the applicable structured data elements (mandatory/mandatory with conditions) as outlined in paragraph 5 of the Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004.

Specifically the following operation can be used on an AMP entity:

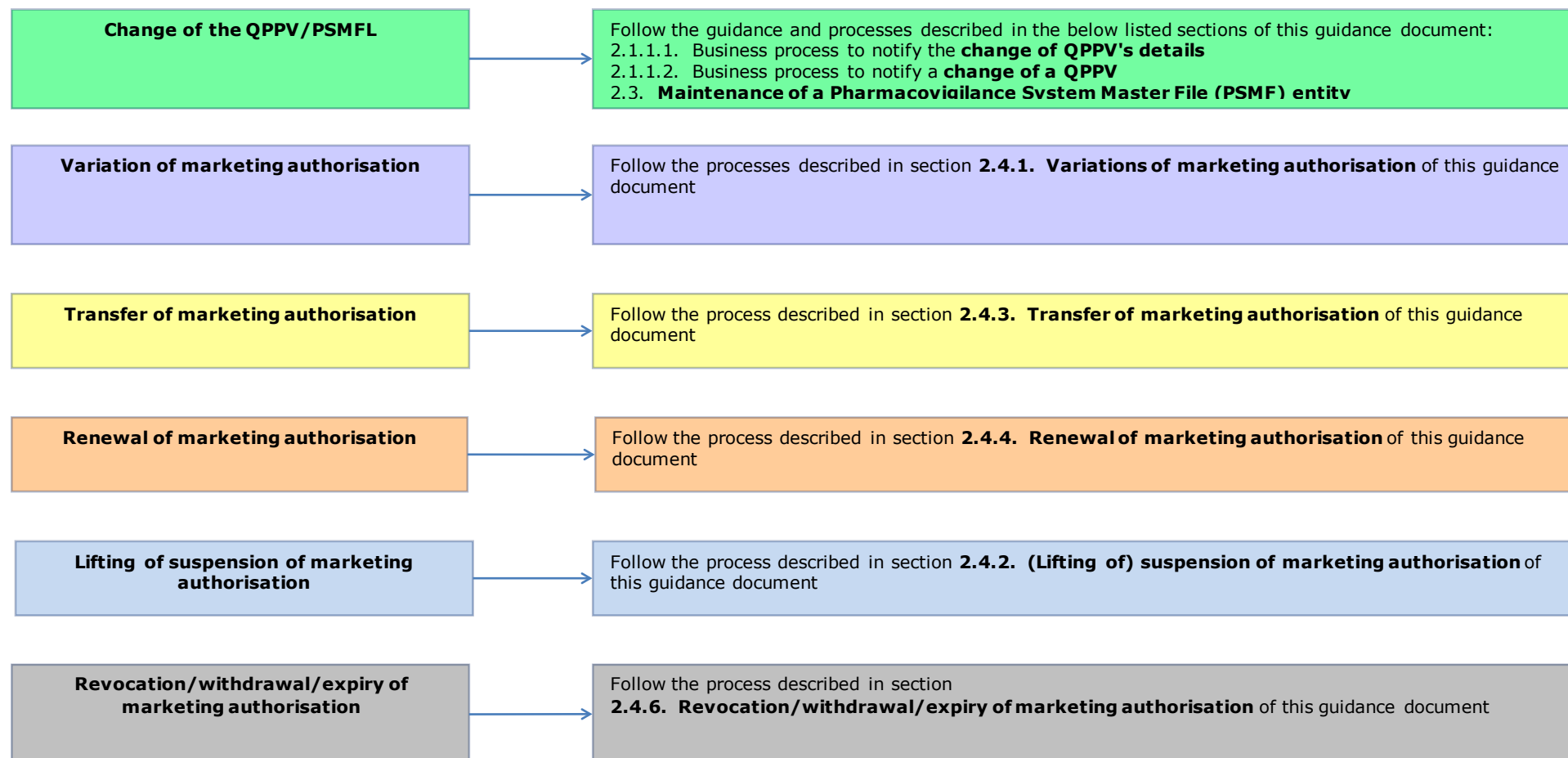
- operation type '**Insert**' (1) must be used to notify changes to the term of the marketing authorisation that trigger a new medicinal product record according to the criteria specified in section [1.1. Initial submission of an authorised medicinal product \(AMP\)](#) of this document and that includes:
 - regulatory procedures that generate new marketing authorisation number (e.g. following a variation where the NCA issues a new marketing authorisation number),
 - extension to the terms of marketing authorisation (e.g. changes to the qualitative and quantitative composition for inclusion of new active substance/adjuvant, changes of the strength/potency, addition of authorised/administrable pharmaceutical form and routes of administration where the NCA issues a new marketing authorisation number),
 - in the context of the transfer of the marketing authorisation, acquiring medicinal product (please refer to transfer of marketing authorisation business process in section [2.4.3. Transfer of marketing authorisation](#) of this document for related information),
 - notification of the renewal of marketing authorisation where the marketing authorisation number has been changed by the competent authority (please refer to the business process described in section [2.4.4.2. Business process - Authorisation number has changed following a renewal](#) of this document);
- operation type '**Update**' (2) must be used to:
 - amend medicinal product information due to variations of the marketing authorisation (please refer to section of this document for related information.
 - correct erroneous data,
 - notify the (lifting of) suspension of the marketing authorisation (please refer to section [2.4.2. \(Lifting of\) suspension of marketing authorisation](#) of this document for related information),
 - notify the renewal of the marketing authorisation where the marketing authorisation number has not been changed by the competent authorities (please refer to section [2.4.4.1. Business process - Authorisation number has not changed following a renewal](#) of this document for related information),
 - extension to the terms of the marketing authorisation; changing the route of administration and where the NCA does not issue a new marketing authorisation number;
- operation type '**Invalidate MA**' (6) must be used to:
 - notify the revocation/withdrawal of the marketing authorisation (please see section [2.4.6. Revocation/withdrawal/expiry of marketing authorisation](#) of this document for related information),
 - in the context of transfer of the marketing authorisation to retire the previously submitted (transferred) medicinal product (please refer to transfer of marketing authorisation business

process in section [2.4.3. Transfer of marketing authorisation](#) of this document for related information),

- notify the renewal of the marketing authorisation where the marketing authorisation number has been changed by the competent authority (please see section [2.4.4.2. Business process - Authorisation number has changed following a renewal](#) of this document for related information);
- operation type '**Nullification**' (4) must be used to flag any medicinal product data previously submitted in the XEVMPD as "non-current" (e.g. duplicated entities or entities provided erroneously).

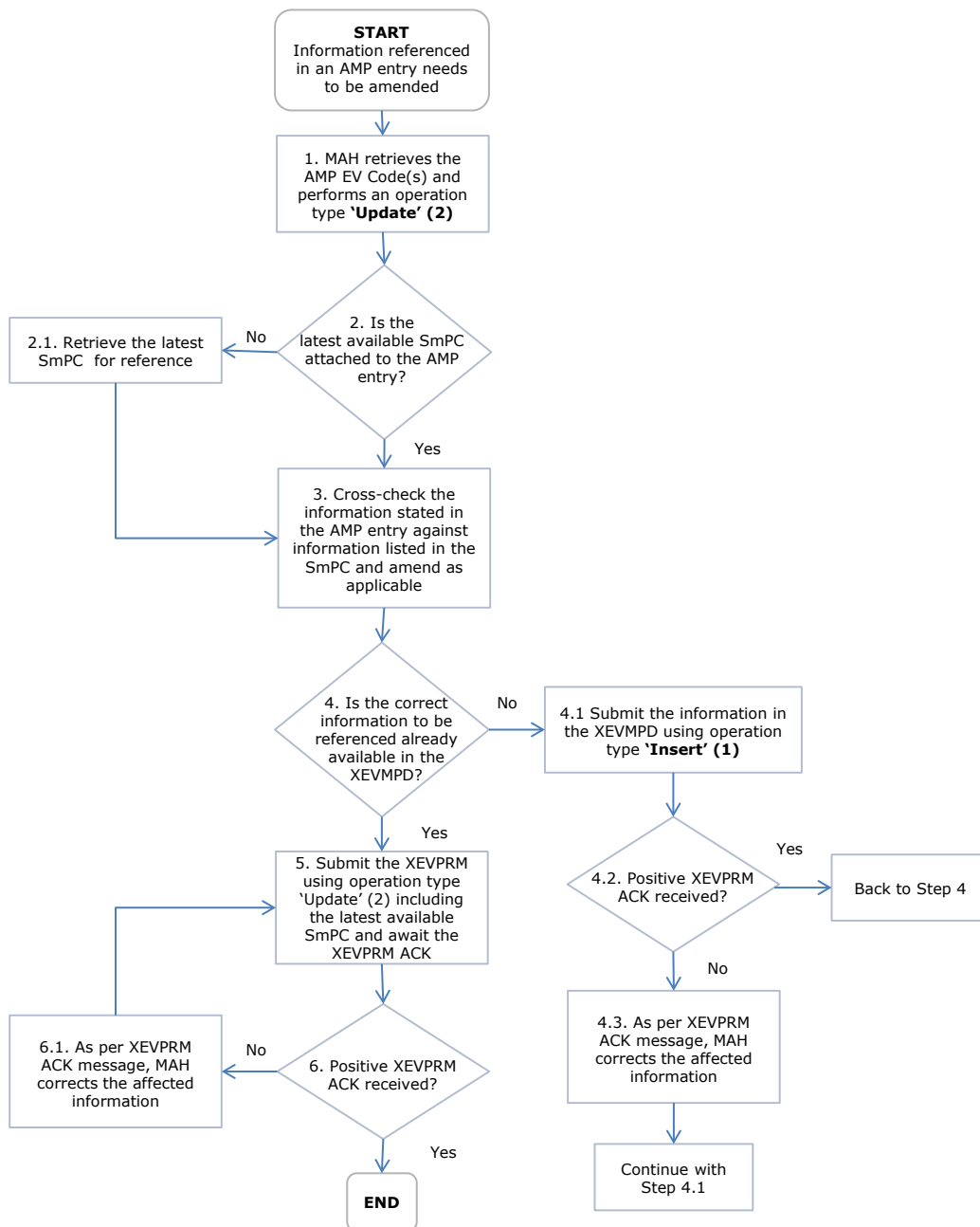
Process map 9 – Business processes to amend medicinal product information in the XEVMPD following a regulatory procedure

Medicinal product information needs to be amended following:



Process map 10 – Amendment of an AMP entity

The following process map describes how to amend an AMP entity in the XEVMPD to ensure that the information within the AMP elements corresponds to the information stated in the attached SmPC:



2.4.1. Variations of marketing authorisation

Operation type '**Update**' (2) must be used, as applicable, to amend incorrectly submitted information (e.g. typos, misspellings and information submitted by mistake) and to submit the latest information on the following product data following a variation procedure:

- (invented) name of the medicinal product;
- description of the pharmacodynamic properties (i.e. the ATC code(s) for the medicinal product);
- details of the marketing authorisation including authorisation status, authorisation country, authorisation procedure, authorisation/renewal date and MRP/DCP/EMA and EU numbers (i.e. to amend incorrectly submitted information);
- marketing authorisation legal basis;
- orphan drug designation;
- medicinal product type as described in section [1.2.12.14. Medicinal product types \(AP.12.MPT.1\)](#) of this document;
- therapeutic indications coded in MedDRA and declaration that the medicinal product is "Authorised for the treatment in children";
- description of the excipient(s);
- description of active substance(s) and adjuvant(s) (i.e. to amend incorrectly submitted information or to reflect a different description of the substance name);
 - Please note that change to the active ingredients and adjuvant refers to line extension and should be notified with an operation type 'Insert' (1);
- description of the strength (amount) of the active substance(s) and adjuvant(s) (i.e. to amend incorrectly submitted information);
 - Please note that change of the strength/potency refers to line extension and should be notified with an operation type 'Insert' (1).
- medical device(s) for combined advanced therapy medicinal product (i.e. in accordance with Regulation (EC) No 1394/2007);
- authorised and administrable pharmaceutical form(s) (i.e. to amend incorrectly submitted information);
 - Please note that change of the authorised and administrable pharmaceutical form(s) refers to line extension and should be notified with an operation type 'Insert' (1).
- route(s) of administration (i.e. to amend incorrectly submitted information);
 - Please note that change of the Route(s) of administration refers to line extension and should be notified with an operation type 'Insert' (1).
- name of qualified person responsible for pharmacovigilance (QPPV);
- location of the pharmacovigilance system master file (PSMF);
- contact information for pharmacovigilance enquiries;

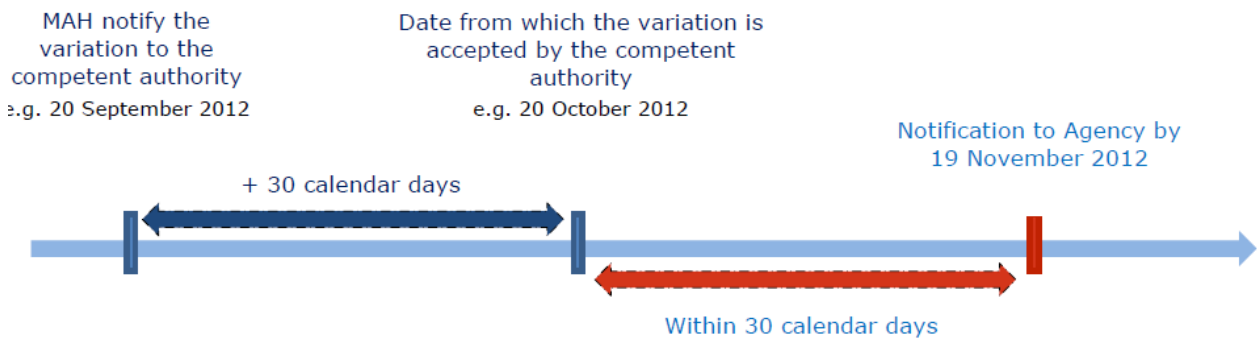
- latest approved SmPC where variations are leading to significant content revision of the following sections of the electronic document and with no impact on XEVPRM structured data elements (mandatory/mandatory with conditions):
 - section 4.1 Therapeutic indications which do not have a direct impact on the MedDRA coding of the indication,
 - section 4.2 Posology and method of administration (other than route of administration),
 - section 4.3 Contraindications,
 - section 4.4 Special warnings and precautions for use,
 - section 4.5 Interaction with other medicinal products and other forms of interaction,
 - section 4.6 Fertility, Pregnancy and lactation,
 - section 4.8 Undesirable effects,
 - section 4.9 Overdose;

Significant revision to these sections are defined as revisions which affect the scientific meaning or information being communicated and does not include minor rephrasing or re ordering due to, for example, a QRD update.

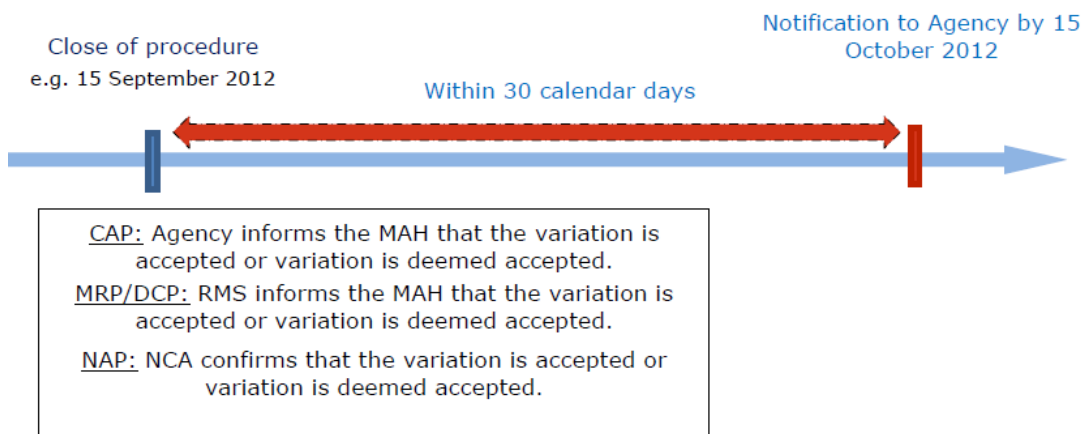
- to correct marketing authorisation holder information (i.e. to amend incorrectly submitted information);
 - Please note that change of the marketing authorisation holder should be notified as transfer of marketing authorisation and therefore the business process outlined in section [2.4.3. Transfer of marketing authorisation](#) of this document.
- (Lifting of) suspension of marketing authorisation;
- notification of the renewal of marketing authorisation where the authorisation number **has not been changed** by the competent authority (please refer to section [2.4.4.1. Business process - Authorisation number has not changed following a renewal](#) of this document).

EXAMPLES of submission dates for variations:

Submission date for Type IA Variations ('Do and Tell') excluding the notification of changes to the QPPV and PSMFL³

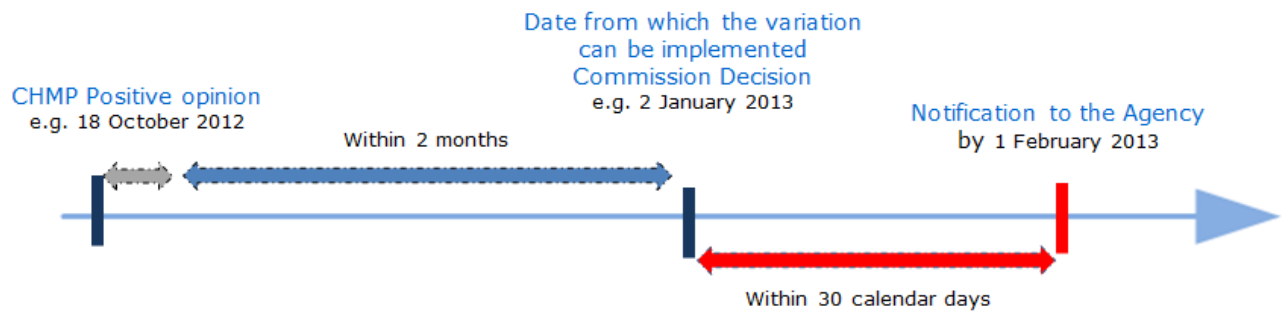


Submission date for Type IB Variations



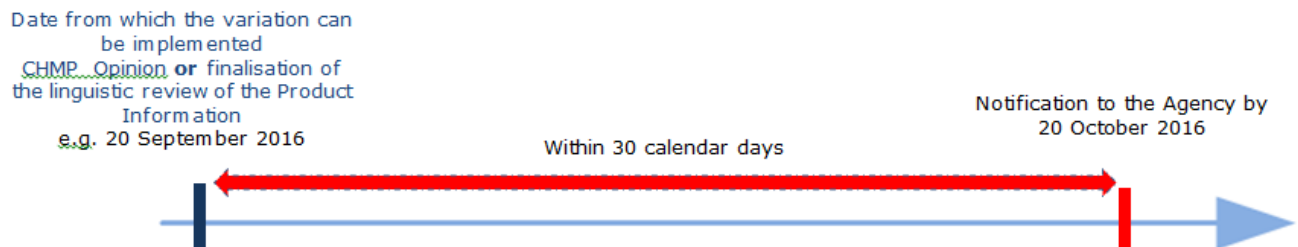
³ Notification of changes related to the QPPV/PSFML are described in sections [2.1.](#) and [2.3.](#)

Submission date for Type II Variations



CAPs (Variations under Art.23(1a)(a) of Variation Regulation):

Notification should take place within 30 calendar days following the date from which the variation can be implemented (= date of Commission Decision)



CAPs (Variations **not falling** under Art.23(1a)(a) of Variation Regulation):

Notification should take place within 30 calendar days following the date from which the variation can be implemented (= CHMP positive opinion **or** the finalisation of linguistic review of the product information, whichever occurs last)*

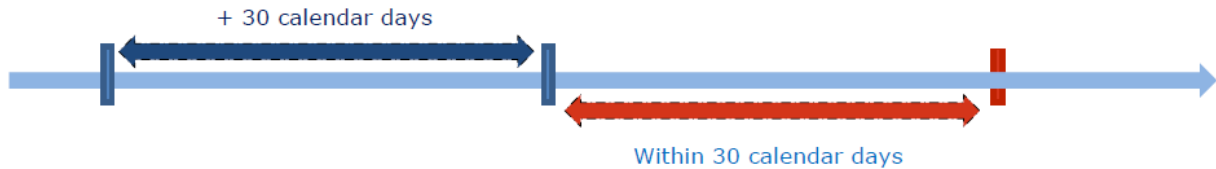
*Note: Variations following the 'weekly start' timetables **do not fall under Art.23(1a)(a) of Variation Regulation**; therefore, the notification of variation to the terms of the marketing authorisation should be submitted within 30 calendar days from the date of variation authorisation (CHMP opinion) **or** from the date that the linguistic review of the product information is completed when this step in the process is applicable.

Submission date for Type II Variations (MRP/DCP)

RMS confirms variation
is accepted
e.g. 20 September 2012

Date from which the variation
can be implemented
e.g. 20 October 2012

Notification to Agency by
19 November 2012



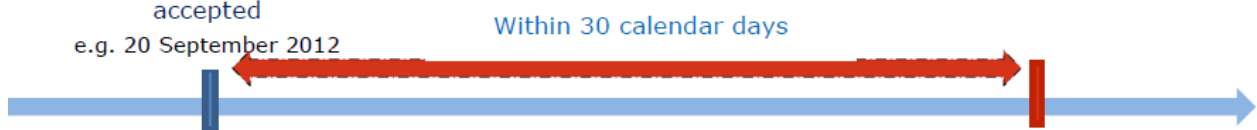
MRP/DCP:

Notification should take place within 30 calendar days following the date from which the variation can be implemented (= date of acceptance of variation by RMS + 30 calendar days). Common approved English text acceptable only if national SmPCs are not available. When the SmPC in the national language becomes available, it must be provided as described in section [2.2.3. Maintenance of authorised medicinal product \(AMP\) entity](#).

Submission date for Type II Variations (NAP)

Date from which the variation
can be implemented
NCA confirms variation is
accepted
e.g. 20 September 2012

Notification to Agency by 20
October 2012



NAP:

Notification should take place within 30 calendar days following the date from which the variation can be implemented (= NCA confirms the variation is accepted)

2.4.1.1. Business process - Authorisation number has changed following a variation

The same business process as described in section [2.4.4.2. Business process - Authorisation number has changed following a renewal](#) should be followed when authorisation number changes following a variation procedure. I.e.:

- the MAH must retire the authorised medicinal product for which the marketing authorisation number is no longer valid by using the operation type 'Invalidate MA' (6);
- in the retired AMP entity:
 - the value "Not Valid – Superseded by Marketing Authorisation Renewal/Variation" (10) must be specified in the data element "Authorisation status" (AP.12.3);
- a new AMP entity must be submitted in the XEVMPD using the operation type 'Insert' (1) with:
 - the new valid authorisation number specified in data element "Authorisation number" (AP.12.4),
 - the value "Valid – Renewed/Varied Marketing Authorisation" (8) must be specified in the data element "Authorisation status" (AP.12.3),
 - the authorisation date as referenced in the applicable attachment must be specified in the data element "Authorisation/renewal date" (AP.12.5),
 - the EV code of the previously submitted AMP entity for which the marketing authorisation number has changed after the variation must be referenced in the XEVPRM section "Previous EV Code" (AP.PEV). The EV Code of the AMP referenced in the "Previous EV Code" (AP.PEV) field must not be a nullified EV Code.

If the variation occurred after a renewal of marketing authorisation and the marketing authorisation number did change following the variation, the same process and principles described above apply.

2.4.1.2. Business process - Authorisation number has not changed following a variation

The MAH retrieves the AMP (based on the assigned EV code) for which the marketing authorisation has been varied and, using an operation type 'Update (2)', amends the medicinal product entity to reflect the changes following the variation (e.g. change of medicinal product name, new indication etc.).

- the authorisation number remains unchanged;
- the authorisation status remains unchanged;
- the authorisation/renewal date remains unchanged.

The MAH checks the XEVPRM ACK to ensure that the AMPs have been updated successfully.

If the variation occurred after a renewal of marketing authorisation and the marketing authorisation number did not change following the variation, the same process and principles described above apply.

2.4.2. (Lifting of) suspension of marketing authorisation

Operation type '**Update**' (2) must be used to notify the suspension of the marketing authorisation or the lifting of suspension of marketing authorisation.

In case of **notification of suspension** of marketing authorisation, the following information must be provided:

- date of the suspension must be specified in the data element "Invalidated date" (AP.12.12);
- the value "Valid – Suspended" (2) must be specified in the data element "Authorisation status" (AP.12.3) before submitting the XEVPRM.

In case of **notification of lifting of suspension** of a marketing authorisation, the following information must be provided:

- no date must be specified in "Invalidated date" (AP.12.12) – this field must be left blank;
- date of lifting of the suspension must be specified in the data element "Info date" (AP.11);
- data element "Authorisation status" (AP.12.3) must continue any other value except "Valid – Suspended" (2) before submitting the XEVPRM.

MAH must check the XEVPRM ACK to ensure that the medicinal product information has been amended (updated) successfully.

2.4.3. Transfer of marketing authorisation

The notification of the transfer of marketing authorisation (i.e. change of the Legal entity of the medicinal product) from the "former MAH" to the "new MAH" is described in this section.

MAH organisations established in the UK should also note Q&A 1. of the ['Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure'](#) document for related information.

The transfer of MA **between organisations registered in EV under separate headquarters** shall be notified to the EMA as follows:

The "former MAH" must:

- retrieve the AMPs (based on the assigned EV codes) for which the marketing authorisation has been transferred and retire the transferred medicinal product entries by using the operation type "Invalidate MA" (6);
- the value "Not Valid – Superseded by Marketing Authorisation Transfer" (11) must be specified in the data element "Authorisation status" (AP.12.3);
- the date of transfer must be specified in the data element "Invalidated date" (AP.12.12).

The "former MAH" checks the XEVPRM Acknowledgment (ACK) to make sure that the AMP has been invalidated successfully.

The "new MAH" must:

- submit new AMP entity for the acquired medicinal products by using the operation type 'Insert' (1);

- the value "Valid – Transferred Marketing Authorisation" (9) must be specified in the data element "Authorisation status" (AP.12.3);
- the date of granting of marketing authorisation by the competent authority must be specified in the data element "Authorisation date" (AP.12.5);
- the EV Code of the AMP entity submitted in the XEVMPD by the former MAH (communicated by the former MAH) must be referenced in XEVPRM section "Previous EV Code" (AP.PEV). The EV Code of the AMP referenced in the "Previous EV Code" (AP.PEV) field must not be a nullified EV Code.
 - in case the former MAH was not compliant with the Article 57 requirements and therefore there is no AMP in the XEVMPD to be referenced (i.e. no previous EV Code was assigned) or the previous MAH nullified the EV Code before the new MAH referenced in their new AMP record, the new MAH can submit the transferred AMP with the 'Insert' (01) operation type and enter value "Valid" (1) in the data element "Authorisation status" (AP.12.3),
 - in case the former MAH did not provide the new MAH with the EV Code of the AMP as entered by the former MAH, please contact the [EMA Service desk](#) to request the EV Code. Please provide the medicinal product name(s), the name of the former MAH organisation and the MAH's EV Code as available in the [XEVMPD Organisation Controlled Vocabulary](#) and the authorisation number(s) of the medicinal product(s) as assigned to the previous MAH. Based on the specified information, the EMA will retrieve the AMP and provide you with the EV Code if available in the XEVMPD.

The new MAH must check the XEVPRM Acknowledgement (ACK) to make sure that the new AMP has been inserted successfully.

For MA transfers **within the same organisation (i.e.: organisations under the same EV headquarter)**, where product data ownership and further maintenance in the XEVMPD is not affected by the marketing authorisation transfer, a simplified process may be followed:

- retrieve the AMP (based on the assigned EV code) for which the marketing authorisation was transferred and apply an operation type 'Update (2)';
- enter the value "Valid – Transferred Marketing Authorisation (9)" in the data element "Authorisation status" (AP.12.3);
- in the data element "Marketing authorisation holder (MAH) code (AP.4)" reference the EV code of the new MAH;
- in the "Previous EV Code" (AP.PEV) section enter the EV Code of the product entity that you are updating;
- submit the XEVPRM and check the XEVPRM Acknowledgement (ACK) to make sure that the AMP information was successfully updated.

EXAMPLES:

"Pharma A" is an MAH established in the Ireland. "Pharma B", which is established in Germany, is registered in EV as an affiliate under the HQ of "Pharma A". Since "Pharma B" is in EV registered under the HQ of "Pharma A" the transfer of MA from "Pharma A" to "Pharma B" may be notified using the simplified process described above.

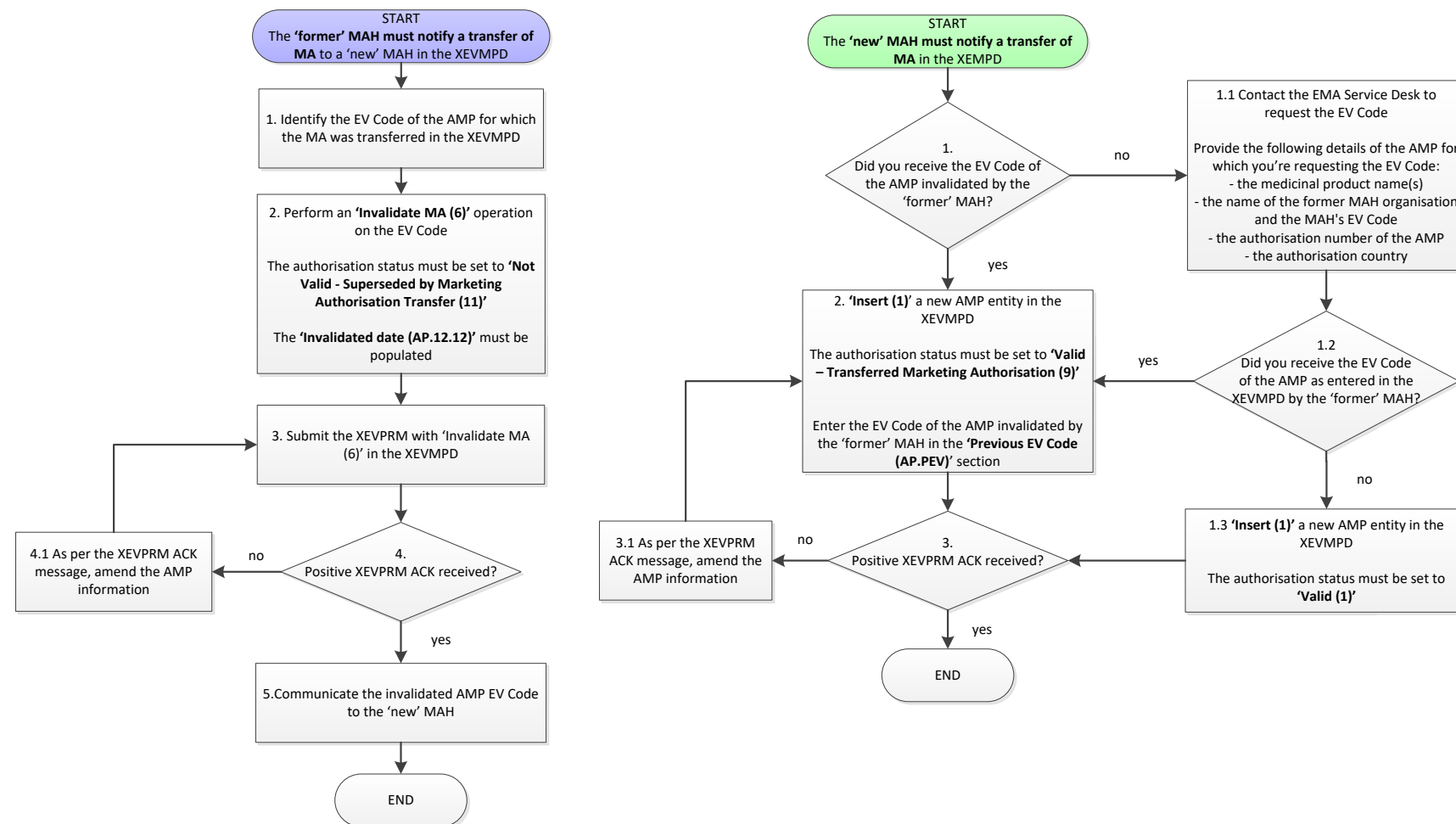
Description	Name/Value
EV Code	PRD120937
Type	Authorised
Is EMA Owned	No
Operation Type	Update
New Owner ID	MAH Pharma B
QPPV	
Master File Location	
PhV enquiry email	
PhV enquiry Phone	
Sender Local Code	
Info Date	
Authorisation Country Code	
Authorisation Procedure	EU authorisation procedures - Centralised Procedure
Authorisation Status	Valid - Transferred Marketing Authorisation

"Pharma C" is an MAH established in the Germany. "Pharma D" is an MAH established in France. Both organisations are registered in EV as affiliates under the HQ of "Pharma E". Since both MAHs are registered in EV under the same HQ the transfer of MA from "Pharma C" to "Pharma D" may be notified using the simplified process described above.

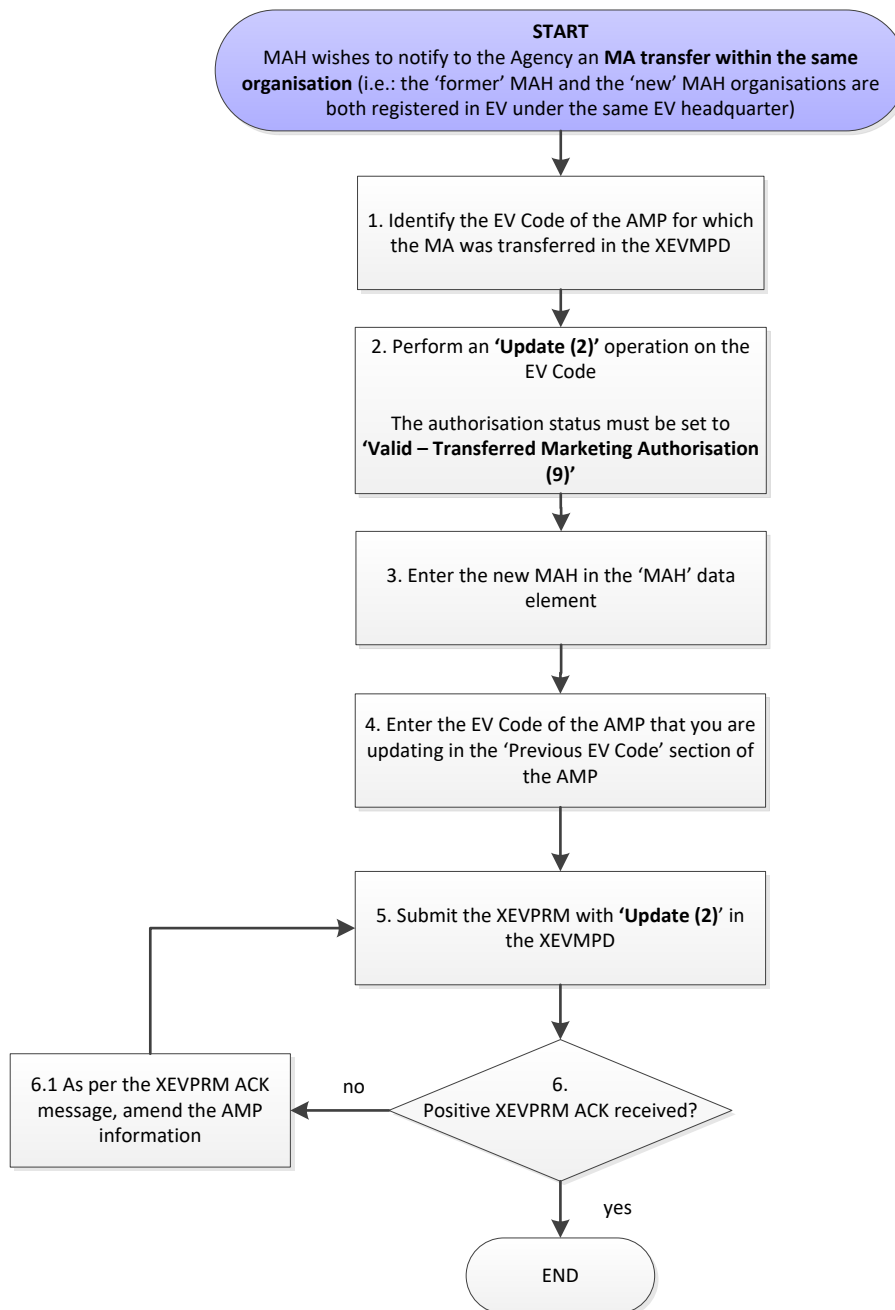
Both processes to notify the transfer of marketing authorisation are described below:

Process map 11 – Transfer of marketing authorisation

Between organisations registered in EV under separate headquarters:



Within the same organisation (i.e.: organisations under the same EV headquarter):



2.4.4. Renewal of marketing authorisation

2.4.4.1. Business process - Authorisation number has not changed following a renewal

As outlined in section of this document, notifications of renewal of marketing authorisations where the marketing authorisation number **has not been changed** by the competent authority must be notified with the operation type 'Update' (2).

The MAH retrieves the AMP (based on the assigned EV code) for which the marketing authorisation has been renewed and changes the **date of authorisation** for the **date of renewal** in the data element "Authorisation/renewal date" (AP.12.5).

The MAH checks the XEVPRM ACK to ensure that the AMPs have been updated successfully.

2.4.4.2. Business process - Authorisation number has changed following a renewal

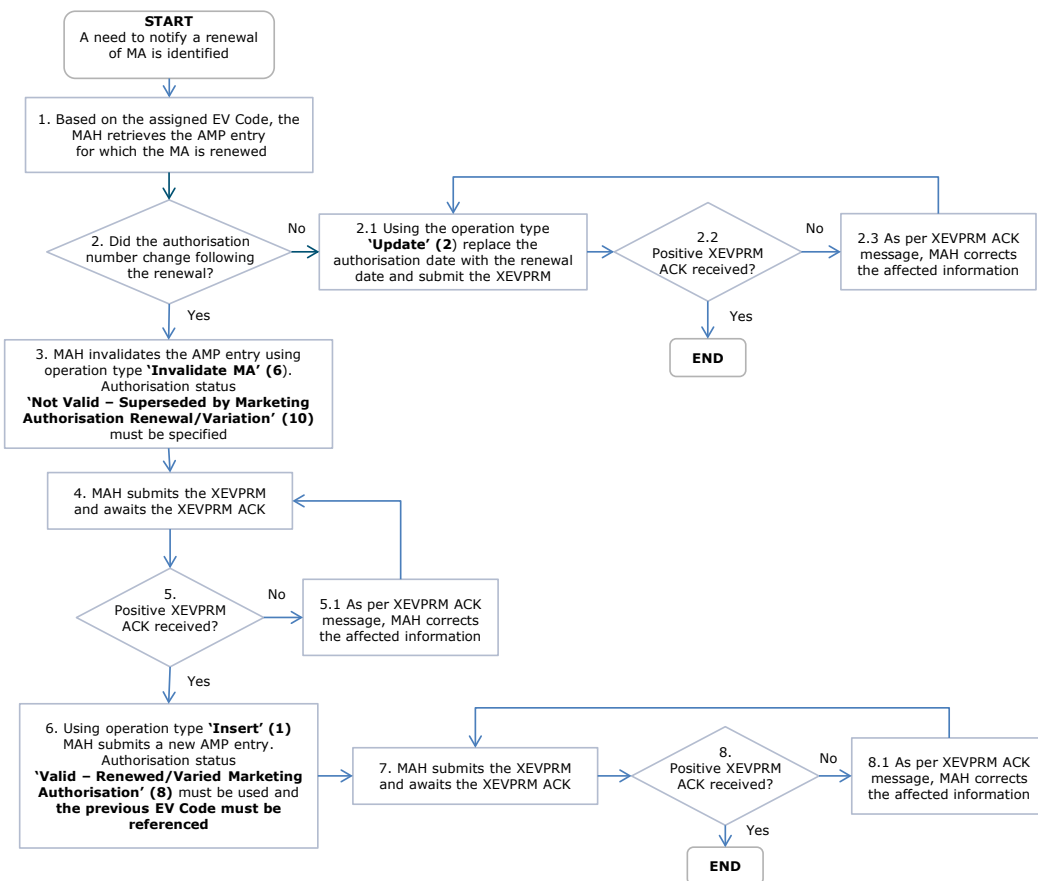
Notifications of renewal of marketing authorisations where the marketing authorisation number **has been changed** by the competent authorities is to be performed as follows:

- the MAH must retire the authorised medicinal product for which the marketing authorisation number is no longer valid by using the operation type 'Invalidate MA' (6);
- in the retired AMP entity:
 - the value "Not Valid – Superseded by Marketing Authorisation Renewal/Variation" (10) must be specified in the data element "Authorisation status" (AP.12.3),
 - the date of renewal must be specified in the data element "Invalidated date" (AP.12.12);
- a new AMP entity must be submitted in the XEVMPD using the operation type 'Insert' (1) with:
 - the new valid authorisation number specified in data element "Authorisation number" (AP.12.4),
 - the value "Valid – Renewed/Varied Marketing Authorisation" (8) must be specified in the data element "Authorisation status" (AP.12.3),
 - the date of the renewal must be specified in the data element "Authorisation/renewal date" (AP.12.5),
 - the EV code of the previously submitted AMP entity for which the marketing authorisation number has changed must be referenced in XEVPRM section "Previous EV Code" (AP.PEV). The EV Code of the AMP referenced in the "Previous EV Code" (AP.PEV) field must not be a nullified EV Code.

The MAH checks the XEVPRM Acknowledgement (ACK) to ensure the successful renewal of the AMP.

Overall renewal of marketing authorisation process is described below.

Process map 12 – Renewal of marketing authorisation



2.4.5. Change of authorisation procedure following a referral

If authorisation procedure has changed from "National" to "MRP" following referral and the marketing authorisation number did not change, marketing authorisation holder retrieves the AMP (based on the assigned EV code) and using operation type 'Update (2)', amends the AMP entity:

- the Authorisation procedure 'EU authorisation procedures – Mutual recognition procedure (3)' must be specified in the "Authorisation Procedure" field (AP.12.2);
- the MR number must be specified in the "MRP/DCP/EMEA number" field (AP.12.7).

2.4.6. Revocation/withdrawal/expiry of marketing authorisation

Operation type '**Invalidate MA**' (6) must be used to notify the revocation/withdrawal/expiry of marketing authorisation:

- the date of revocation or withdrawal or expiry must be specified in the data element "Invalidated date" (AP.12.12);
- one of the "Not Valid" statuses must be specified (as applicable) in the data element "Authorisation status" (AP.12.3) before sending the XEVPRM.

The MAH checks the XEVPRM ACK to ensure that the AMP has been invalidated successfully.

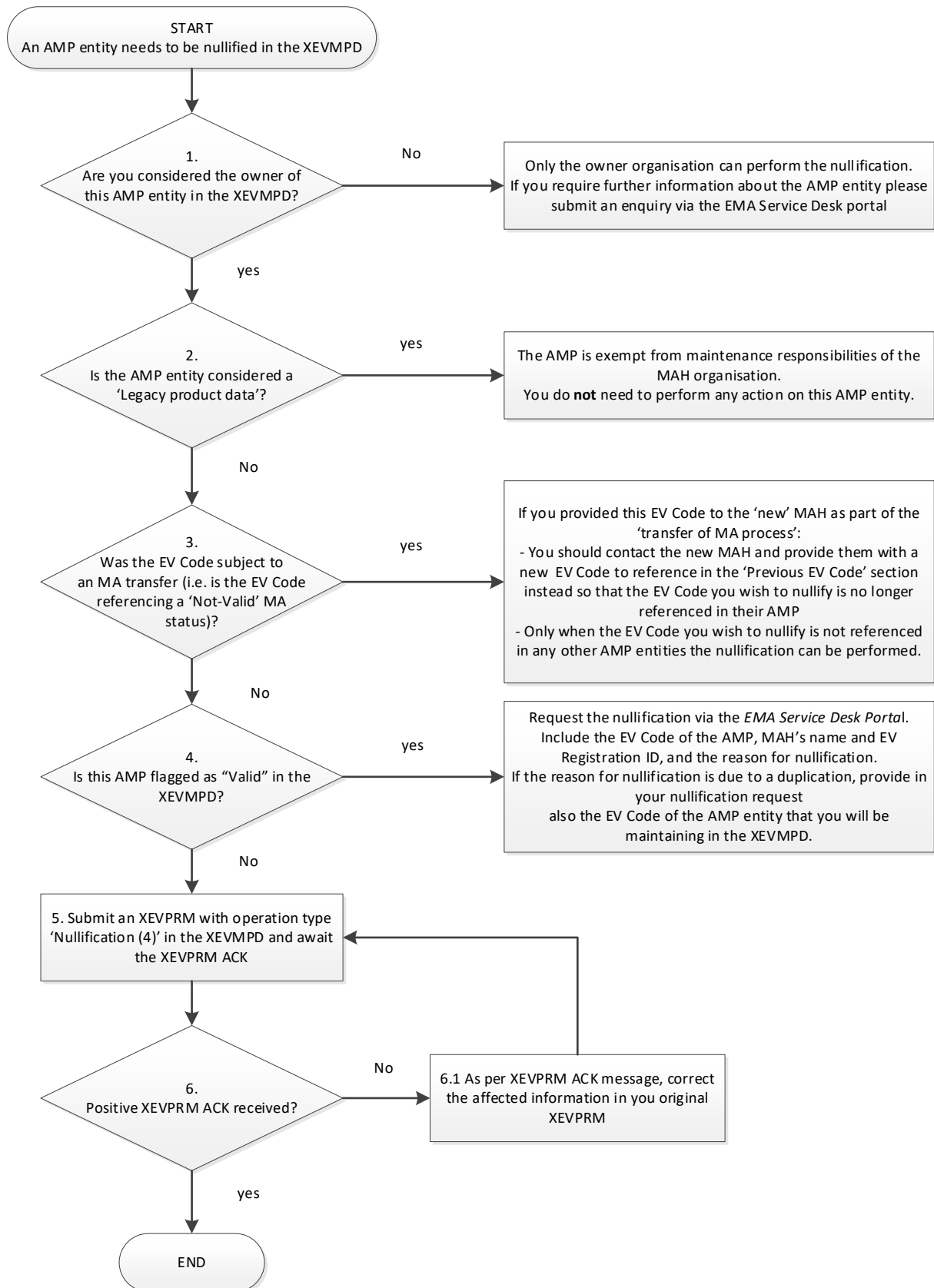
2.4.7. Nullification of AMP entities

Marketing authorisation holders should flag as "nullified" AMP entities created by mistake, e.g. duplicated entities (the same medicinal product information was submitted multiple times, multiple EV Codes were assigned) or entities provided erroneously (e.g. they were not supposed to be submitted).

- Only the owner of the product data in the XEVMPD (i.e. the organisation that submitted the data and/or its HQ) can nullify such data.
- Nullification is not allowed on AMP entities, which are considered Legacy product data [see [Legacy product data in the eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPD\)](#) for related information]. Such product entities should not be maintained by the MAH.
- Nullification is not allowed on AMP entities which were flagged as "Valid" in the XEVMPD (i.e. the "Product Validity" field displays the value "Valid") following a quality control check by the Agency [see [Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57\(2\) of Regulation \(EC\) No 726/2004](#) for related information].
 - only the EMA can nullify such AMP entities. Please submit a nullification request using the EMA Service Desk portal (<https://servicedesk.ema.europa.eu>), stating the EV Code(s) of the AMP(s) you wish to nullify, your organisation's name and EudraVigilance registration ID, and the reason for nullification.

Since all AMP entities flagged as "Valid" are used to support signal management activities (e.g. codification of ICSRs), before they are nullified, the EMA needs to check that a "substitute" record is available in the XEVMPD. If the reason for nullification is due to duplication, the EV Code of the AMP entity that the MAH will be maintaining in the XEVMPD must also be provided as part of the nullification request. If a nullification of more than 10 AMP entities is requested, please provide the EV Codes in an Excel spreadsheet.

Process map 13 – Nullification of an AMP entity



2.5. Nullification of XEVMPD entities

An XEVMPD entity, which is duplicated (i.e. multiple EV Codes are assigned to the same entity), obsolete (the entity is not/will not be referenced in any product submissions) or erroneously submitted (e.g. the entity was not supposed to be submitted) can be flagged as 'non-current' by submitting an XEVPRM with the operation type 'Nullification' (4) or 'Update (2)' depending on the type of entity and if the entity is referenced in any AMPs or not.

In general, MAHs may nullify entities, which they own in the XEVMPD. I.e. the entities submitted from the organisation ID under which they are registered in the EV Registration database, and/or its HQ and/or the related affiliates. MAHs can therefore nullify:

- AMP entities;
- MAH entities;
- Proposed ATC codes;
- Proposed pharmaceutical forms;
- Proposed routes of administration;
- PSMFL entities.

There are however restrictions related to the nullification of entities referenced in other entities.

The above listed entities may be nullified by their owner organisations only if they are **not referenced in any other XEVMPD entities (e.g. AMPs)** or they are only **referenced in XEVMPD entities that are nullified**.

If the entity you wish to nullify is referenced in **AMPs with any of the 'Valid' marketing authorisation statuses**, the AMPs must first be updated to reference another entity before the nullification is technically possible.

If the entity you wish to nullify is referenced in **AMPs that were invalidated** [i.e. the 'Authorisation status (AP.12.3)' field references any of the 'Not-valid' values], the process described in the below listed sections of this document should be followed:

- If you wish to nullify an MAH entity that is referenced in an invalidated AMP, please follow the process described in [Process map 6 – Notifying an MAH entity](#) as 'non-current'
- If you wish to nullify a PSMFL entity that is referenced in an invalidated AMP, please follow the process described in [Process map 8 – Notifying a PSMFL entity as 'non-current', Step 2.1.B](#)
- If you wish to nullify an AMP entity that was a subject to a marketing authorisation transfer and communicated to the new MAH, please refer to [Process map 13 – Nullification of an AMP entity](#)
- If you wish to nullify a proposed ATC Code, proposed pharmaceutical form or a proposed route of administration, please refer to [Process map 14 – Nullification of XEVMPD entities](#).

There are also restrictions on nullifications of AMPs, please refer to the overall process described in [Process map 13 – Nullification of an AMP entity](#)

Process map 14 – Nullification of XEVMPD entities

