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Information Management

Data quality control methodology for data submitted under Article 57(2) of Regulation (EC) No.726/2004

[1] MDMS contact point was replaced with EMA Service Desk.

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1. Purpose

The purpose of this document is to describe the data quality framework for Article 57(2) data. The data quality framework for Article 57(2) data aims at data compliance with the requirements set out in the legislation, the Legal notice on the implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004 (hereinafter referred to as "Legal notice") and guidance documents published by European Medicines Agency (EMA) on the 'Guidance documents' webpage. It ensures that the business needs are efficiently and effectively addressed based on reliable, up to date and accurate data to support the EMA business processes. This document defines clear ownership and responsibility of data quality with specific stakeholders.

This document is aimed to provide industry with the basis on how to quality control the Article 57(2) data prior to submission via the eXtended EudraVigilance Product Report Message (XEVPRM) as referred into paragraph 1(a) of the Legal notice, based on the experience gained by the EMA after performing a pilot-validation exercise on the initial data submitted by 2 July 2012. More guidance may be provided after the validation of data submitted during the transition maintenance phase.

It is expected that in the future, this document will be revised to better align to the concepts of master data management around information on medicines rather than be solely focused on Article 57(2). To this end, a future revision would include legislation relating to investigational medicinal products (IMPs) and implementation of standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP).

2. Intended audience

To achieve the purpose of this document it is necessary for each "type" of stakeholder to review this document to ensure alignment. The intended audience of this document are the users of the Article 57(2) data and specifically:

- marketing-authorisation holders (MAHs);
- any other users of the Article 57 database.

3. Scope

In line with the requirements referred to in paragraph 1(a) and following the detailed guidance as referred to in paragraph 1(b) of the Legal notice, the following information on medicinal products authorised for human use including medicinal products authorised for the treatment in children are within the scope of the data quality framework for Article 57(2) data:

1. authorised medicinal product (AMP):
    - 1.1. name(s) of the medicinal product;
    - 1.2. marketing-authorisation holder information;
    - 1.3. authorisation details (country, dates, numbers, status, indication, legal basis, medicinal product type);
    - 1.4. pharmacovigilance details;
    - 1.5. printed product information (for use in QC of data);
2. pharmaceutical product:

2.1. qualitative and quantitative composition;

2.2. routes of administration;

2.3. authorised and administrable pharmaceutical form;

2.4. medical device;

2.5. medicinal product drug ingredients.

This document focuses on authorised medicinal products; therefore aspects related to investigational medicinal products (IMPs) are out of scope. IMPs QC methodology principles may be included in future versions.

4. Business Processes relying on Article 57(2) data

From 16 June 2014 until ISO IDMP implementation commencing in July 2016, marketing-authorisation holders are required to amend the authorised medicinal product submitted in the XEVPRM format in compliance with the requirements of Article 57 of Regulation (EC) 726/2004 following the guidance and processes provided in the Detailed Guidance; i.e. hereby referred to as the "transition maintenance phase" [transition to the ISO Identification of Medicinal Product (IDMP) standards implementation].

A long-term strategy in view of the implementation of the ISO IDMP standards is currently being developed by the EMA, taking into account the potential impact on the European Regulatory Network, EU stakeholders and international partners.

The scope of the transition maintenance phase submission is:

- to collect up-to-date information on authorised medicinal products initially submitted under Article 57(2) requirements in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) by correcting any erroneously submitted information;
  - For Gateway user it includes the reconciliation of the medicinal product data against the new EV Code provided in the XEVMPD controlled vocabularies (CVs) following the quality control activities performed by the EMA (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;
- 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 date of authorisation (i.e. 15 calendar days from the date of notification of the granting of the marketing authorisation by the competent authority).

The transition maintenance phase as described in this guidance document will enable the EMA to establish a complete and reliable database on medicinal product information to support the following areas:

- performance of data analysis at the EMA, specifically:
  - EudraVigilance (EV) data analysis and signal management,

  - establish a complete list of medicinal product and active substance information to be support the coding of such information reported in Individual Case Safety Reports (ICH 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,
  - provide EV users with a complete list of medicinal product and active substance information as reporting possibilities in Individual Case Safety Reports (ICH ICSRs); release of data to MAHs in accordance with regulation (EC) No 726/2004, Article 24;
- communicate efficiently with EMA stakeholders by means of:
  - providing information on medicines in the EU via the European medicines web portal,
  - granting access to EudraVigilance data proactively and reactively (e.g. ADR dashboard),
  - supporting EU and international data exchange on demand (e.g. Provide information on medicines in EU to international regulators),
  - supporting the Pharmacovigilance Risk Assessment Committee (PRAC) for any communication with its stakeholders (e.g. identification of impacted MAHs and their contact details to target PRAC communications).

The intended use of each data elements is described in section *10. Annex*.

Examples of the use of Article 57 data are provided as follow:

- simplification of adverse reaction reporting for MAHs and implementation of access to EudraVigilance by MAHs to the extent necessary to support their pharmacovigilance activities;
- decision making on the B/R ratio of medicinal products: e.g. correct EudraVigilance data analysis to support referrals, correct information on products impacted by referral decisions;
- efficiency within the EU Regulatory Network: e.g. maintenance of the EURD list to coordinate the submission of PSURs to support the single assessment;
- transparency and sharing of information: e.g. access to all the EU medicinal product information on the EU medicinal web portal and publication of correct aggregated ADR information (www.adrreports.eu);
- reporting of ADRs and other structured data: e.g. MAHs/NCAs can incorporate Art 57(2) data in their systems before submitting ADRs, allowing a perfect identification of the medicinal product information within the ADR.

Article 57 stakeholders include:

- marketing-authorisation holders (MAHs);
- the European Medicines Agency and its committees;
- the EU national competent authorities as part of the communication;
- EU public;

- EU International partners.

5. Stakeholder Roles in the Data Management

As outlined in the Legal Notice, the following roles apply as regard the Article 57 product data management:

Marketing-authorisation holders shall:

- use the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) as the format to electronically submit to the EMA information on all medicinal products for human use authorised in the Union;
- after 2 July 2012, submit information on medicinal products for new marketing authorisations in the Union to the EMA immediately 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);
- ensure that information on all medicinal products for human use authorised in the Union, which is submitted electronically to the Agency using the format and content as referred to in point 1, 3 and 4 of the Legal notice is accurate and up to date;
- electronically notify to the Agency information on any amendments to the terms of the marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal no later than 30 calendar days from the date of which the amendments have been authorised;
- as of 1 February 2016 notify changes in the qualified person responsible for pharmacovigilance (QPPV), including contact details (telephone and fax numbers, postal address and email address) and changes to the pharmacovigilance system master file (PSMF) location (street, city, postcode, country) to the competent authorities through the Article 57 database immediately and no later than 30 calendar days from the date the change applies;
- respond to requests of the Agency immediately and no later than 15 calendar days following receipt of such request.

The EMA will perform an overall review of the quality and integrity of the medicinal product information submitted. The process performed by the EMA is in line with the description provided in section *7. Information quality metrics/scorecard* of this document.

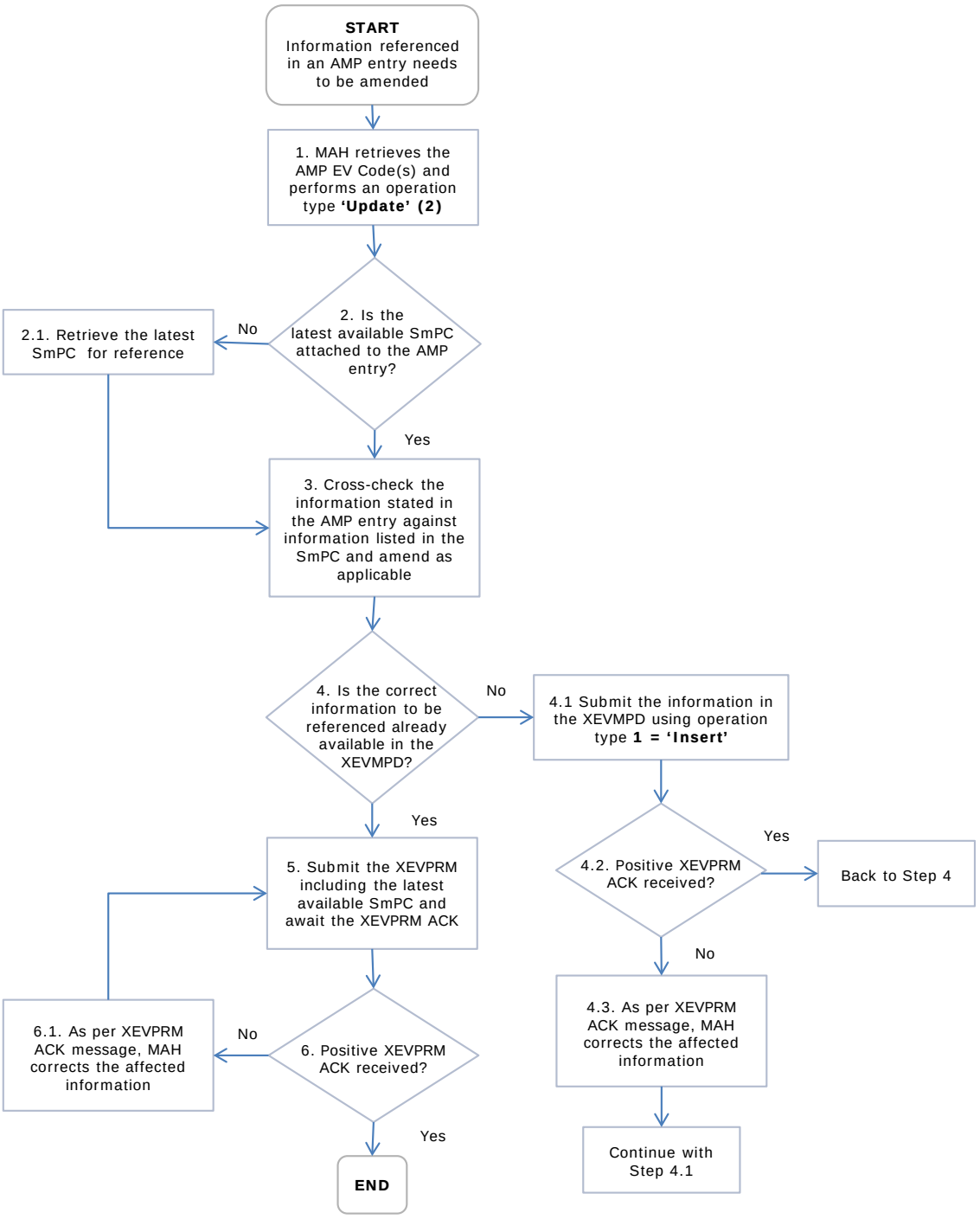
6. Quality control

It is envisaged that all medicinal product records should undergo data quality control before being submitted into the XEVMPD as part of Article 57 initial data submission. Thereafter, and referring to the Article 57 data maintenance submission, where there is a need for corrections or the provision of additional information, the affected data elements should be quality controlled. The outlines of the quality control process have been published in November 2014 and are available on in the document Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No. 726/2004

Any data elements falling into the scope of the Agency's business areas and described in section *4. Business Processes relying on Article 57(2) data* are subject to quality control.

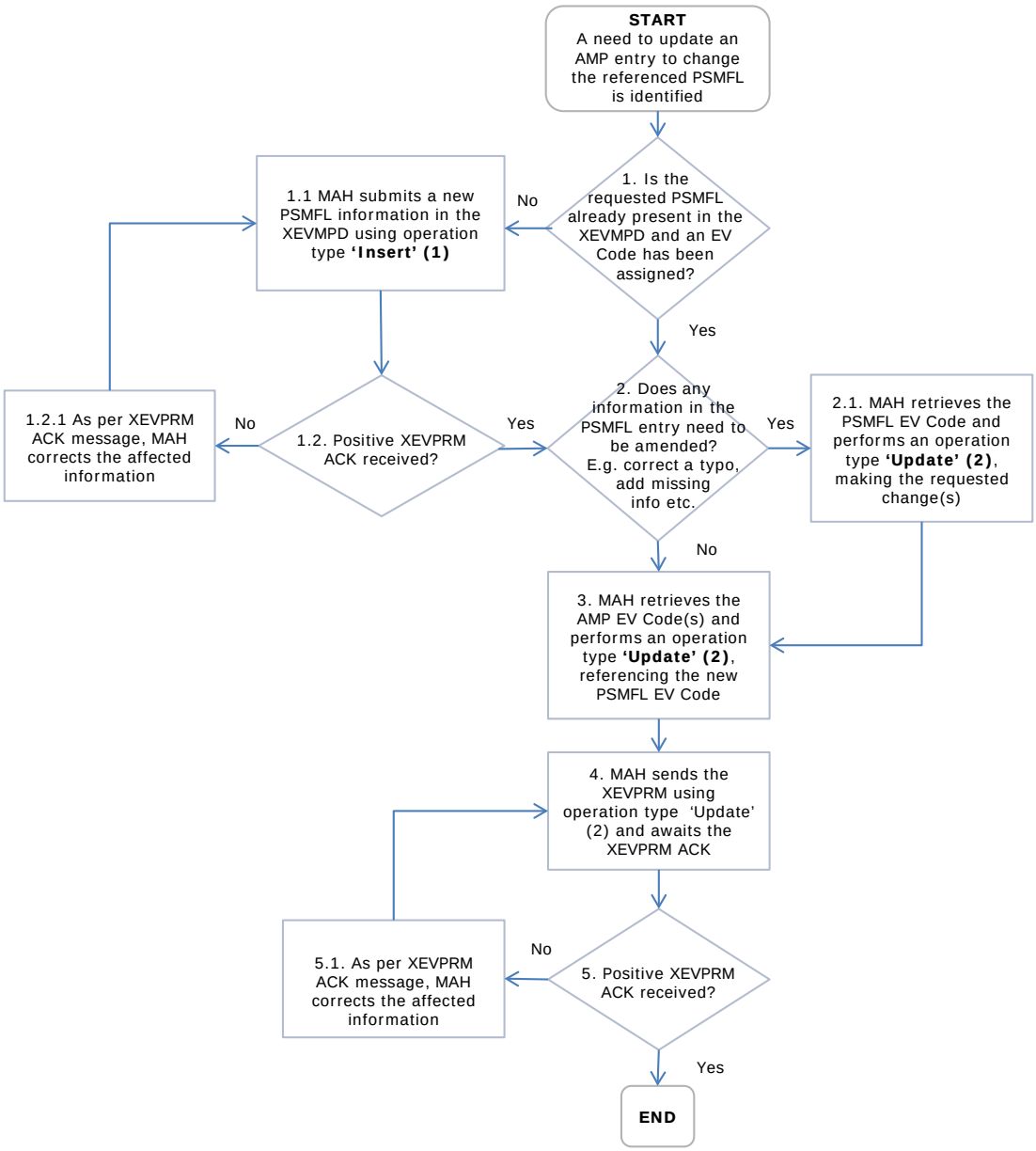
The product validation process when the information referenced in an AMP entry needs to be amended according to the latest the summary of product characteristics (SmPC) is described below.

Figure 1. Bringing authorised medicinal product entries up to date



As an example, the business process where the referenced PSMFL changes is described below.

Figure 2. Update of medicinal product entry to change PSMFL

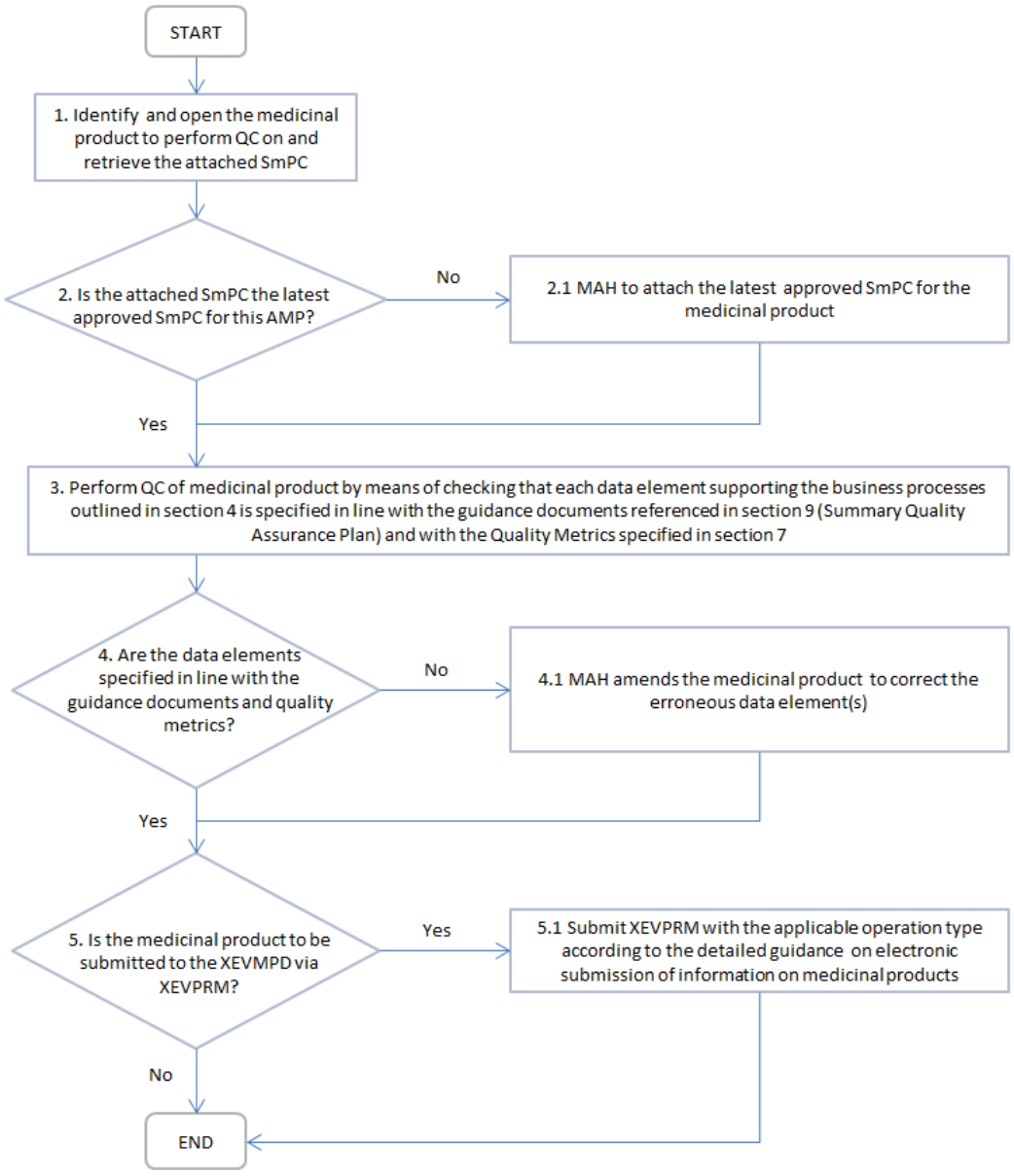


The quality control (QC) of Article 57 medicinal product data elements is to be performed following the below steps:

1. medicinal products submitted in the XEVMPD production environment are retrieved in the database;
2. the SmPC is downloaded for each medicinal product entry;
3. the products are classified as nationally authorised products (NAPs), centrally authorised products (CAPs) or mutually/decentrally authorised products (MRPs/DCPs) by checking the "Authorisation Procedure" data element (AP.12.2) of the XEVPRM.

The following business process applies:

Figure 3. Overview of quality control process to be performed by MAHs in the context of data maintenance (transition maintenance phase)



7. Information quality metrics/scorecard

MAHs should validate the information provided in the Article 57 data elements and perform quality control according to the scoring values describe below that they may implement in their business processes.

- 0 (= incorrect):
  - data element is wrongly populated,
  - data element is blank whereas it should be populated,
  - data element is populated whereas it should be blank;
- 1 (= correct):
  - data element is correctly populated (as applicable).

As regard the acceptance metrics of the individual Article 57 data elements, please refer to section *10. Annex*.

8. Information security and control

In the eXtended Eudravigilance Medicinal Product Dictionary (XEVMPD), a set of information is based on the use of controlled vocabularies (CVs). Currently the XEVMPD controlled vocabularies are accessible (not downloadable) via the data entry tool provided by the EMA (so called "EVWEB interface") designed to be used by small and medium enterprise(s). Other (and larger) pharmaceutical industries can generate the electronic product report message (i.e. XEVPRM) by means of in-house entry tool and send the XEVPRM into the EMA Gateway. For the latter users, the controlled vocabularies are essential for the implementation of such lists in their in-house system and for the adequate compilation of XEVPRMs to be submitted.

There are 2 types of controlled vocabularies in the XEVMPD:

- official standard term lists controlled vocabularies maintained by EMA/maintenance organisation;
- Article 57 controlled vocabularies maintained by the MAHs.

8.1. Official standard term lists controlled vocabularies maintained by EMA/maintenance organisation

The following CVs are standard term lists maintained by external maintenance organisation and are available as such in the XEVMPD (i.e. without any additional ad-hoc terms):

- MedDRA:
  - MedDRA list is published and maintained by the MedDRA MSSO. Summary of changes for each MedDRA version are published by the MedDRA MSSO,
  - In the data entry tool provided by the EMA, MedDRA is updated bi-annually with the official release of each MedDRA versions;
- country code:
  - the country code is maintained by ISO (ISO-3166). The list is publicly available and freely downloadable at http://www.iso.org/iso/iso-3166-1_decoding_table';

- two-letter language code:
  - the two-letter language code is maintained by ISO (ISO 639-1). The list is publicly available and freely downloadable at http://www.sil.org/iso639-3/codes.asp?order=639_1&letter=%25 and http://www.loc.gov/standards/iso639-2/php/code_list.php,
  - the official standard term lists controlled vocabularies are not subject to any QC but, once released from the official maintenance organisation, are updated in the XEVMPD/Article 57 database;
- ATC:
  - the ATC list is published and maintained by the WHO Collaborating Centre for Drug Statistics Methodology. Summary of changes for each ATC version are published by WHO,
  - in the data entry tool provided by the Agency, ATC list is updated with the official release of each ATC versions,
  - in addition to the ATC standard term list, the values "NOTASSIGN" and "NOTAPPLIC" were added to the official list to allow the selection of such values when the ATC code is not assigned or not applicable to the authorised/registered medicinal product;
- standard (authorised/administrable) pharmaceutical form:
  - the standard pharmaceutical form controlled vocabulary is populated and maintained by the EMA. The XEVMPD value is the EDQM standard term value whilst the unique identifiers (i.e. EV Codes) are randomly and automatically assigned by the EV system upon request;
- standard route of administration:
  - the standard route of administration controlled vocabulary is populated and maintained by the EMA. The XEVMPD value is the EDQM standard term value whilst the unique identifiers (i.e. EV Codes) are randomly and automatically assigned by the EV system upon request.

The following controlled vocabularies are populated and maintained by the EMA. Unique identifiers (i.e. EV Codes) are randomly and automatically assigned to each value by the EV system as necessary.

- approved substance:

  To insert a new approved substance or add a new translation or synonym to an existing approved substance (i.e. update of an existing substance), a request should be sent to ~~MDMS@ema.europa.eut~~ the EMA Service Desk (https://servicedesk.ema.europa.eu/). Please refer to Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD): Submission of substance information for further information.
- authorisation procedure list;
- substance class;
- authorisation status list;
- XEVMPD concentration type list;
- medical devices;
- unit of presentation description;
- unit of measurement description.

The following lists serve the description of the strength of the medicinal product:

- XEVMPD amount prefix unit;
- XEVMPD amount numerator unit;
- XEVMPD amount denominator unit.

The values and codes of the above lists are published and maintained by the Unified Code for Units of Measure (UCUM) and are freely available at http://unitsofmeasure.org/. Any additional values and codes are generated using the same 'logic' as UCUM. In accordance with the UCUM copyright notice and license available at http://unitsofmeasure.org/wiki/TermsOfUse, "(2) *Users shall not modify the Licensed Materials and may not distribute modified versions of the UCUM table (regardless of format) or UCUM Specification. Users shall not modify any existing contents, fields, description, or comments of the Licensed Materials, and may not add any new contents to it.*"

Requests for the addition of new standard terms (including new units of measurement/presentation) in the XEVMPD Controlled Vocabularies should be submitted via the EMA Service Desk portal (https://servicedesk.ema.europa.eu) with supporting documentation (e.g. SmPC).

8.2. Article 57 controlled vocabularies maintained by the MAHs

The following controlled vocabularies are populated and maintained by the MAHs in the context of the Article 57 electronic data submission. Unique identifiers (i.e. EV Codes) are randomly and automatically assigned to each value by the EV system upon request:

- organisation;
- reference source;
- PSMFL;
- proposed (administrable/authorised) pharmaceutical form;

  The proposed pharmaceutical form controlled vocabulary is populated and maintained by external XEVMPD users. Unique identifiers (i.e. EV Codes) are randomly and automatically assigned by the EV system upon request.
- proposed route of administration;
- The proposed route of administration controlled vocabulary is populated and maintained by external XEVMPD users. Unique identifiers (i.e. EV Codes) are randomly and automatically assigned by the EV system upon request.

The MAH has the responsibility to maintain and ensure the quality of the above CVs terms and details. The process to maintain such information is outlined in *Figure 1. Bringing authorised medicinal product entries up to date* (steps 4-4.3) and *Figure 2. Update of medicinal product entry to change PSMFL* (steps 1-1.2 and 2-2.1) in section *6. Quality control*. Please also refer to the section *2.2.2. Maintenance of XEVMPD Controlled Vocabularies (CVs) submitted by the MAH* of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

9. Summary Quality Assurance Plan

This section covers the existing documentation to be used to deliver quality assurance in the data to be provided under Article 57(2):

- Article 57 Guidance documents available at the Guidance documents webpage:
  - Legal notice,
  - Detailed guidance documents on electronic submission of information on medicinal products,
  - Article 57(2) requirements: Frequently asked questions,
  - controlled vocabularies (CVs)/CVs quality control;
- reporting requirements for marketing-authorisation holders;
- XEVMPD training;
- XEVMPD e-learning;
- XEVMPD Data-Entry Tool (EVWEB) User Manual.

The business rules in place (for the purpose of data quality) are referenced in Chapter 3.I: XEVPRM technical specifications of the detailed guidance documents on electronic submission of information on medicinal products.

10. Annex

Table 1. Intended use and quality metrics of Article 57 data elements

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
AP.2	(Product) ev_code		1.2.2. EV Code (AP.2)	Data analysis Regulatory actions and legal obligation Communication with stakeholders	N/A
AP.12.13	legalbasis	LN Point 3(iv) Details of the marketing authorisation and the status	Check that this field specifies the Legal Basis as indicated in 1.2.12.13. Legal basis (AP.12.13).	Data analysis Regulatory actions and legal obligation	0 or 1
AP.12.MPT.1	producttypecode	LN Point 3(v) A description of the medicinal product type	Check that this field specifies the Medicinal Product Type as indicated in 1.2.12.14. Medicinal product types (AP.12.MPT.1).	Data analysis Regulatory actions and legal obligation	0 or 1
AP.APF.1	authpharmformcode	LN Point 3(x) The authorised (…) pharmaceutical form(s)	Check that this field specifies the authorised pharmaceutical form(s) of the medicinal product as indicated in 1.2.14. Authorised pharmaceutical form (AP.APF.1).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.4	mahcode	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the MAH code as indicated in 1.2.4. Marketing authorisation holder (MAH) code (AP.4). The appropriate EVCode of the Organisation must be selected.	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
O.2	name_org	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the MAH name as indicated in 1.6.2. Organisation name (O.2).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
O.4	(MAH) ev_code		1.6.4. EV Code (O.4)	Data analysis Regulatory actions and legal obligation Communication with stakeholders	N/A
O.6	address	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the address as indicated in 1.6.6. Address (O.6).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
O.7	city	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the city as indicated in 1.6.7. City (O.7).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
O.8	state (region)	LN Point 3(iii) Details of the marketing authorisation holder	1.6.8. State (O.8).	Outside the scope of the prioritised business areas	If provided, 0 or 1
O.9	postcode	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the postcode as indicated in 1.6.9. Postcode (O.9).	Data analysis Regulatory actions and legal obligation Communication with	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
				stakeholders	
O.10	countrycode	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the country code as indicated in 1.6.10. Country Code (O.10).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
O.19	sme_status	LN Point 3(iii) Details of the marketing authorisation holder	Check that this field specifies the SME status as indicated in 1.6.15. SME status (O.19).	Data analysis Regulatory actions and legal obligation	0 or 1
O.20	sme_number		1.6.16. SME number (O.20)	Outside the scope of the prioritised business areas	If provided, 0 or 1
AP.5	qppvcode	LN Point 4(i) Name, address and contact details of the Qualified Person Responsible for Pharmaco-vigilance (QPPV)	Check that this field specifies the QPPV code as indicated in 1.2.5. Qualified Person responsible for Pharmacovigilance (QPPV) code (AP.5).	Regulatory actions and legal obligation Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
AP.6	mflcode	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	Check that this field specifies the MFL code as indicated in 1.2.6. Pharmacovigilance System Master File Location (PSMFL) code (AP.6).	Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
		guidance in Module II – Pharmacovigilance system master file of the Good Vigilance Practice(s).			
AP.7	enquiryemail	LN Point 4(ii) Contact e-mail for pharmacovigilance enquiries	Check that this field specifies the Pharmacovigilance enquiry email as indicated in 1.2.7. Pharmacovigilance enquiry email (AP.7).	Communication with stakeholders	0 or 1
AP.8	enquiryphone	LN Point 4(iii) Contact phone number for pharmacovigilance enquiries	Check that this field specifies the Pharmacovigilance enquiry phone as indicated in 1.2.8. Pharmacovigilance enquiry phone (AP.8).	Communication with stakeholders	0 or 1
AP.11	infodate	LN Point 3(iv) e) (…) the date of the lifting of the suspension where applicable	1.2.11. Info date (AP.11)	Outside the scope of the prioritised business areas	If provided, 0 or 1
AP.12.1	authorisationcountrycode	LN Point 3(iv) c) Country of marketing authorisation	Check that this field specifies the Authorisation Country Code as indicated in 1.2.12.1. Authorisation country code (AP.12.1).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
AP.12.2	authorisationprocedure	LN Point 3(iv) a) Marketing authorisation procedure	Check that this field specifies the Authorisation Procedure as indicated in 1.2.12.2. Authorisation procedure (AP.12.2).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.12.3	authorisationstatus	LN Point 3(iv) f) Marketing authorisation status	Check that this field specifies the Authorisation status as indicated in 1.2.12.3. Authorisation status (AP.12.3).	Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.12.4	authorisationnumber	LN Point 3(iv) d) Marketing authorisation number	Check that this field specifies the Authorisation number as indicated in 1.2.12.4. Authorisation number (AP.12.4).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.12.5	authorisationdate	LN Point 3(iv) e) Authorisation/renewal date (…) where applicable	Check that this field specifies the Authorisation or Renewal date as indicated in 1.2.12.5. Authorisation/renewal date (AP.12.5).	Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.12.7	mrpnumber	LN Point 3(iv) g) Mutual-recognition/(de)centralised or national authorisation procedure number	Check that this field specifies the MRP, DCP or EMEA number as indicated in 1.2.12.7. MRP/DCP/EMEA number (AP.12.7).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
AP.12.8	eunumber	LN Point 3(iv) d) Marketing authorisation number	Check that this field specifies the EU number as indicated in 1.2.12.8. EU number (AP.12.8).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.12.9	orphandrug	LN Point 3(iv) h) Orphan drug designation	1.2.12.9. Orphan drug status (AP.12.9)	Outside the scope of the prioritised business areas	If provided, 0 or 1
AP.12.10	intensivemonitoring		1.2.12.10. Additional monitoring (AP.12.10)	Outside the scope of the prioritised business areas	If provided, 0 or 1
AP.12.12	withdrawndate	LN Point 3(iv) i) Date of withdrawal/revocation/suspension of the medicinal product authorisation, where applicable	Check that this field specifies Withdrawn/Invalidated date as indicated in 1.2.12.12. Withdrawn/Invalidated date (AP.12.12), if applicable.	Regulatory actions and legal obligation	0 or 1
AP.13.1	productname	LN Point 3(i) A description of the (invented) name of the medicinal product	Check that this field specifies the Full presentation name as indicated in 1.2.13.1. Full Presentation Name (AP.13.1).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.13.2	productshortname	LN Point 3(i) A description of the	Check that this field specifies the Product Short Name as indicated in 1.2.13.2. Product Short	Data analysis Regulatory actions and	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
		(invented) name of the medicinal product	Name (AP.13.2).	legal obligation Communication with stakeholders	
AP.13.3	productgenericname	LN Point 3(i) A description of the (invented) name of the medicinal product (Directive 2001/83/EC Common or scientific name accompanied by a trade mark or the name of the MAH)	Check that this field specifies the Product INN/Common Name as indicated in 1.2.13.3. Product INN/Common Name (AP.13.3).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.13.4	productcompanyname	LN Point 3(i) A description of the (invented) name of the medicinal product (Directive 2001/83/EC Common or scientific name accompanied by a trade mark or the name of the MAH)	Check that this field specifies the Product Company Name as indicated in 1.2.13.4. Product Company Name (AP.13.4).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.13.5	productstrength	LN Point 3(i) A description of the (invented) name of the medicinal product	Check that this field specifies the Product Strength Name as indicated in 1.2.13.5. Product Strength Name (AP.13.5).	Data analysis	0 or 1
AP.13.6	productform	LN Point 3(i) A description of the	Check that this field specifies the Product Form Name as indicated in 1.2.13.6. Product Form	Data analysis	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
		(invented) name of the medicinal product	Name (AP.13.6).		
AP.13.7	packagedesc		1.2.15. Package description (AP.13.7)	Outside the scope of the prioritised business areas until ISO IDMP implementation (2016)	If provided, 0 or 1
AP.14	comments	LN point 3(vi) b) Declaration that the medicinal product is "authorised for the treatment in children"	Check that this field specifies a comment as indicated in 1.2.16. Comment (AP.14), if applicable.	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.1	pharmformcode	LN Point 3(x) The (…) administrable pharmaceutical form(s)	Check that this field specifies the administrable pharmaceutical form(s) of the medicinal product as indicated in 1.2.17.1. Administrable Pharmaceutical Form (PP.1).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.AR.1	adminroutecode	LN Point 3(xi) A description of the posology and method of administration, which shall include Route(s) of administration	Check that this field specifies the Route of Administration as indicated in 1.2.17.2. Administration route (PP.AR.1).	Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.ACT.1	substancecode	LN Point 3 (vii): a) A description of the active substance(s) (…) where applicable	Check that this field specifies the Active Ingredient as indicated in 1.2.17.4. Active ingredient substance code (PP.ACT.1).	Data analysis Regulatory actions and legal obligation Communication with	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
				stakeholders	
PP.ACT.2-14		LN Point 3 (vii) b) A description of the strength (amount) of the active substance(s) (…)	Check that this field specifies the strength of the active ingredient as indicated in 1.2.17.5. Active ingredient substance strength, 1.2.17.6. Active ingredient concentration type Code (PP.ACT.2) and 1.2.17.7. Active ingredient substance value(s) (PP.ACT.3-14).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.ADJ.1	substancecode	LN Point 3 (vii) a) A description of the (…) adjuvant(s), where applicable	Check that this field specifies the Adjuvant as indicated in 1.2.17.10. Adjuvant substance code (PP.ADJ.1), if applicable.	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.ADJ.2-14		LN Point 3 (vii) b) A description of the strength (amount) (…) (including adjuvants)	Check that this field specifies the strength of the adjuvant as indicated in 1.2.17.11. Adjuvant substance strength, if applicable. The same principles as described in section 1.2.17.6. Active ingredient concentration type Code (PP.ACT.2) and 1.2.17.7. Active ingredient substance value(s) (PP.ACT.3-14) apply to the description of strength of adjuvants.	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
PP.EXC.1	substancecode	LN Point 3 (viii) A description of the excipient(s)	Check that this field specifies the Excipient as indicated in 1.2.17.8. Excipient substance code (PP.EXC.1).	Regulatory actions and legal obligation Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
PP.EXC.2-14			1.2.17.9. Excipient substance strength The same principles as described in section 1.2.17.6. Active ingredient concentration type Code (PP.ACT.2) and 1.2.17.7. Active ingredient substance value(s) (PP.ACT.3-14) apply to the description of strength of excipients should the MAH wish to submit it.	Outside the scope of the prioritised business areas	If provided, 0 or 1
PP.MD.1	medicaldevicecode	LN Point 3(ix) A Description of the medical device(s) for combined advanced therapy medicinal product in accordance with Regulation (EC) No 1394/2007 as applicable	Check that this field specifies the Medical Device as indicated in 1.2.17.12. Medical Device Code (PP.MD.1), if applicable.	Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.ATC.1	atccode	LN Point 3(ii) a) The ATC code(s) for the medicinal product	Check that this field specifies the ATC code as indicated in 1.2.18. Product ATC Code(s) (AP.ATC.1).	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.IND.1	meddraversion	LN Point 3(vi) a) Therapeutic indication(s) (coded in MedDRA)	Check that this field specifies the MedDRA version as indicated in 1.2.19.1. MedDRA version (AP.IND.1).	Data analysis Communication with stakeholders	0 or 1

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
AP.IND.2	meddralevel	LN Point 3(vi) a) Therapeutic indication(s) (coded in MedDRA)	Check that this field specifies the MedDRA Level as indicated in 1.2.19.2. MedDRA version (AP.IND.2).	Data analysis Communication with stakeholders	0 or 1
AP.IND.3	meddracode	LN Point 3(vi) a) Therapeutic indication(s) (coded in MedDRA)	Check that this field specifies the MedDRA term as indicated in 1.2.19.3. MedDRA version (AP.IND.3).	Data analysis Communication with stakeholders	0 or 1
AP.PEV.1	devevcode		Check that this field specifies the previous EV code as indicated in 1.2.20. Previous EV Code (AP.PEV), if applicable	Data analysis Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.PPI.1	attachmentcode	LN Point 3 (xii): An electronic copy of the latest approved Summary of Product Characteristics including version date, document reference number(s) and document language(s)	Check that this field specifies the product attachment as indicated in 1.2.21. AMP - Printed Product Information (PPI) Attachments and 1.2.21.1. Attachment EV Code (AP.PPI.1)	Regulatory actions and legal obligation Communication with stakeholders	0 or 1
AP.PPI.2	validitydeclaration	LN Point 3 (xii): An electronic copy of the latest approved Summary of Product	1.2.21.2. Attachment validity declaration (AP.PPI.2)	Outside the scope of the prioritised business areas	N/A

Art 57 data elements ref. code	Art 57 data elements ref. name	Legal basis/Legal Notice (LN)	Reference to detailed guidance – chapter 3.II	Intended use of Art 57 data element	Quality metrics (score)
		Characteristics including version date, document reference number(s) and document language(s)			