EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

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 5: eXtended EudraVigilance Product Report Acknowledgement Message

Version 3.5

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Version 2.0	1 September 2011	1 September 2011

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(*) e-submission of information on medicines - Structured Substance Information (SSI) - (chapter 4 currently not applicable)

Summary of Changes

Following the publication of version 3.4 in October 2015, changes were made in the below section(s) of this document; the changes are highlighted in red:

- 1.3. Acknowledgement Structure

1. Extended EudraVigilance Product Report Acknowledgement Message (XEVPRM_ACK)

1.1. Acknowledgement Message

Upon receipt of an XEVPRM, the Agency will generate an Acknowledgement Message (XEVPRM_ACK). Following the submission of an XEVPRM, Gateway user organisations receive an MDN acknowledgement generated automatically by the European Medicines Agency's ESTRI Gateway.

Once an XEVPRM is processed by the EudraVigilance system, Gateway/WEB Trader user organisations receive an XML message acknowledgement which contains the results of the electronic submission of the XEVPRM, and the result of the operation type requested for each medicinal product entity within that XEVPRM.

As of 27 October 2014, the XEVPRM_ACK was amended to include additional information in the "operationresultdesc" field regarding the validation of the submitted authorised medicinal product entity.

- Version number has been added (e.g. *"Version 1"*);
- The following text is now also displayed: *"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 XXXX Version [Version Number] / [Date and Time]"."*

From 4 November 2015, an additional acknowledgement is generated for each authorised medicinal product entity that was quality controlled (i.e. "validated") by the EMA.

1.2. XEVPRM_ACK XSD Location

The technical specification of the XEVPRM_ACK is contained within the XML Schema Definition (XSD) file which is located here: http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd.

1.3. Acknowledgement Structure

The XEVPRM_ACK contains two levels of acknowledgements:

The **1st level** is the Message Acknowledgement (*messageacknowledgement - Section A*). This level summarises the results of the electronic submission of medicinal product information via the XEVPRM. The possible results at this level are:

- All medicinal product reports have been loaded into the database;
  - All the reports contained in the XEVPRM have been processed successfully (coded as a '01' acknowledgement).
- XEVPRM Error, not all information has been loaded successfully into the database;
  - Some reports contained in the XEVPRM have not been processed successfully (coded as a '02' acknowledgement). The errors are listed in the reportacknowledgement (*Section B of the XEVPRM_ACK*).

- Serious error, no data has been loaded into the database;
  - The message could not be processed due to one or more errors in the XML file (coded as a '03' acknowledgement). This could be due to errors in the XML structure, the schema validation or non-compliance with the business rules.

The **2nd level** is the Report Acknowledgement (*reportacknowledgement - Section B*).

This level summarises the result of the operation type assigned to each medicinal product entity in an XEVPRM. This section also contains the mapping between the 'local number' and the 'EV Code' for those product entities that have been loaded successfully.

For the medicinal product entities that are not loaded successfully, the section *reportcomments* contains the list of errors encountered during the loading process.

The description text also includes additional information on the validation of data performed by the EMA and informing on:

- The applicable version number
  - Medicinal product submitted in an XEVPRM with an operation type 'Insert (1)' is assigned with a version number (i.e. version number 1). Any subsequent amendment(s) to the medicinal product entity via an operation type 'Update (2)', 'Invalidate MA (6)' or 'Nullification (4)' lead to a new version number being assigned,
  - MAHs can view each individual version available for the EV Code of their AMP entity in the sections "Previous Versions"/"Subsequent Versions" within the AMP entity in EVWEB;
- The quality control activity (i.e. validation) that the EMA will perform
  - The text *"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 XXXX Version [Version Number] / [Date and Time]"."*

    Please note that *"…further acknowledgement…"* referenced in the above message will be implemented in the production environment as of 4 November 2015.

The file name of the (1st and 2nd level) XEVPRM_ACK is in the format:
"ack_" + <file name sent by the MAH without .zip> + ".xml".

It is generated per each XEVPRM message and sent to the sender organisation ID that submitted the XEVPRM within 24 hours since the initial submission.

From 4 November 2015, an additional (so called **3rd level**) acknowledgement file is generated for version(s) of an authorised medicinal product entity that was validated by the EMA:

- If **no changes were performed by the EMA on an authorised medicinal product entity** submitted by the MAH, the file name of the (3rd level) acknowledgement is in the format: "validated-" + <Sender ID of the Validated Version> + "-"+ <EV Code> + "-"+ <Validated Version Number> + "-" + <Date and Time> + ".xml";
  - The Message Number (messagenumb) is in the format: "Product Validated as submitted " + <EV Code> + " Version "+ <Validated Version Number> + " / " + <Date and Time>

- The Original Message Number (originalmessagenumb) is in the format:
  <EV Code> + " Version "+ <Validated Version Number>
- The Operation Result Description (operationresultdesc) is in the format:
  "Product validated successfully as submitted.".

- If **changes were performed by the EMA on an authorised medicinal product entity** submitted by the MAH, the file name of the (3rd level) acknowledgement will be in the format:
  "ackval" + "_"+ <EV Code> + "_"+ <New Version Number> + ".xml"
  - The Message Number (messagenumb) ise in the format:
    "Product validated following EMA edit of data " + <EV Code> + " Version "+ <Validated Version Number> + " / " + <Date and Time>
  - The Original Message Number (originalmessagenumb) is in the format:
    "EMA edit of data " + <EV Code> + " Version "+ <Version Number used as base for the Changes>
  - The Operation Result Description (operationresultdesc) is in the format:
    "Entity updated successfully"
    "Version " + <New Version Number>
    "Product validated following EMA edit of data. Please note that your product data was not deemed valid as submitted and was edited as part of the validation process as follows:"
    +
    "Product Versions Changes"
    + <the list of changes made to each field>

The (3rd level) acknowledgement is generated for each individual validated version of an authorised medicinal product entity (i.e. one AMP entity per XEVPRM XML Acknowledgement) and sent to the sender organisation ID that submitted the version of the AMP entity used as base for the validation (with changes) when a version of an AMP is validated by the EMA:

- The first validation of a newly submitted AMP is performed within 2 weeks since the initial submission of the AMP.
- There is no defined timeline for a subsequent validation following an update of the AMP information. This is due to large volumes of data and prioritisation of newly entered products. Therefore, re-validation of previously validated AMPs is performed as needed and max within 2 years since last validation.
- No futher validation is performed on AMP records that are nullified or invalidated in the XEVMPD.

MAH organisations using **WEB Trader** (for both EVWEB application users and users posting via the 'EV-Post function'), can retrieve the additional (3rd level) acknowledgement from their WEB Trader Inbox/Archived Inbox.

MAH organisations using in-house solutions (i.e. **Gateway Users**), were advised to enhance their systems to allow the receipt of the additional acknowledgement and should liaise with their Gateway providers with regards to where the additional acknowledgement is stored.

When a product information has been amended by the EMA, to optimize the process and the parser activity, the system has been modified to reject any AMP entity containing information identical to the

information submitted by the MAH in the previous version of the AMP entity, which was subject to a validation (with changes) by the EMA.

I.e. MAH submits an AMP (version 1 is created); EMA performs validation with changes (version 2, which is not identical to version 1, is created); MAH submits a new version (identical to version 1) - this version (version 3) is rejected by the parsers; MAH submits a new version (not identical to version 1) - this version is accepted by the parsers (version 4 is created).

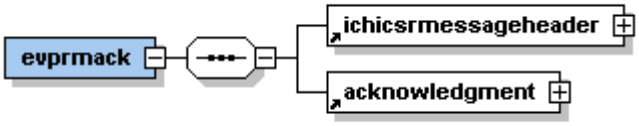
- If an AMP entity was rejected due to the above-described reason, the operation result description (operationresultdesc) will be in the format:
  "Please note that your product data is deemed not valid as submitted because it matches a previous version of the product that was edited by EMA in order to be validated.".

In the figures below the ***mandatory sections/data elements*** are presented as boxes with ***solid lines*** and the ***non-mandatory sections/data elements*** as boxes with ***dotted lines***.

The XEVPRM acknowledgment XML schema is presented in Figure 1 - XEVPRM Acknowledgement.

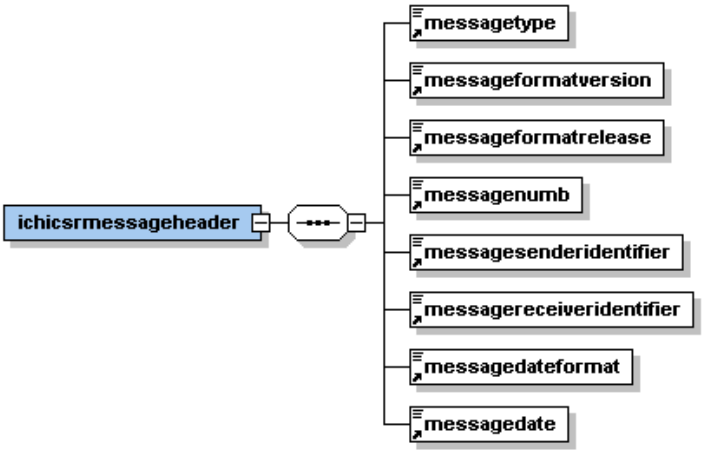
1.3.1. General Structure

Figure 1 - XEVPRM Acknowledgement



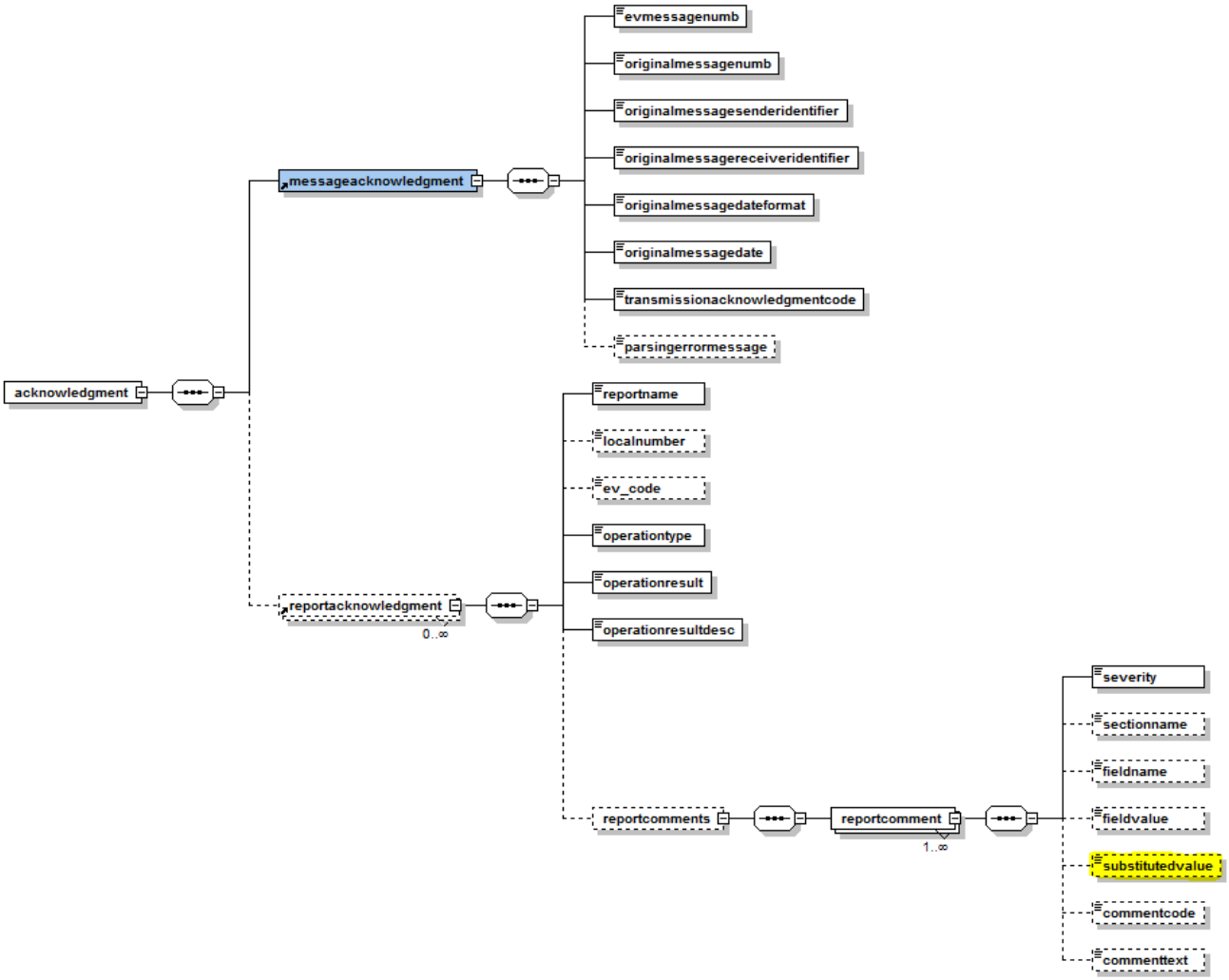
1.3.2. Acknowledgement Message Header

Figure 2 - XEVPRM Acknowledgement - Message Header



1.3.3. Acknowledgment Sections

Figure 3 - XEVPRM Acknowledgement - Acknowledgement Section



1.4. XEVPRM Acknowledgement Elements Description

The XEVPRM_ACK data elements are presented below with a reference to the cardinality of each element.

The cardinality indicates the number of occurrences of the data elements:

- 0:1: optional data element with up to one occurrence;
- 0:N: optional data element with one or more occurrence;
- 1:1: mandatory data element with only one occurrence;
- 1:N: mandatory data element with one or more occurrence.

Data element reference	Data element name	Type	Cardinality	Data element description
A	evprmack *See section 1.3.1.*		1:1	
B	ichicsrmessageheader *See section 1.3.2.*		1:1	The message header section It refers to the Sender Organisation, the Receiver Organisation, the type of information being transmitted and the transmission date. This section requires the establishments of an EDI trading partnership agreement that will help define the message number, sender ID, receiver ID and message date.
B.1	messagetype	xs:string (16)	1:1	The message type contains information on the type of information being transmitted. The value of this field shall be "EVPRMACK".
B.2	messageformatversion	xs:string (3)	1:1	The message format version contains the version number of the schema.
B.3	messageformatrelease	xs:string (3)	1:1	The message format release contains the release number of the message format version of the schema.
B.4	messagenumb	xs:string (100)	1:1	The message number is a unique tracking number assigned to a specific XEVPRM transmitted by the sender organisation. This message number is unique to the sender organisation.

Data element reference	Data element name	Type	Cardinality	Data element description
B.5	messagesenderidentifier	xs:string (60)	1:1	The message sender identifier uniquely identifies the sender of the XEVPRM, e.g. company name identifier or regulatory authority name identifier.
B.6	messagereceiveridentifier	xs:string (60)	1:0	The message receiver identifier uniquely identifies the receiver of the XEVPRM, e.g. company name identifier or regulatory authority name identifier.
B.7	messagedateformat	xs:string (3)	1:1	The original message date: The unique value admitted is "204" corresponding to "CCYYMMDDHHMMSS"
B.8	messagedate	xs:string (14)	1:1	Message Date: the message date on which the XEVPRM was initiated.
E	messageacknowledgment *See section 1.3.3.*		1:1	The message acknowledgment section
E.1	evmessagenumb	xs:string (100)	1:1	The message number assigned to the XEVPRM that the acknowledgement message refers to.
E.2	originalmessagenumb	xs:string (100)	1:1	The message number specified by the sender organisation in the XEVPRM to which the acknowledgement message refers to.
E.4	originalmessagesenderidentifier	xs:string (60)	1:1	The message sender identifier specified by the sender organisation in the XEVPRM to which the acknowledgement message refers to.
E.5	originalmessagereceiveridentifier	xs:string (60)	1:1	The message receiver identifier specified by the sender organisation in the XEVPRM to which the acknowledgement message refers to.

Data element reference	Data element name	Type	Cardinality	Data element description
E.6	originalmessagedateformat	xs:string (3)	1:1	The message date format specified by the sender organisation in the XEVPRM to which the acknowledgement message refers to.
E.7	originalmessagedate	xs:string (14)	1:1	The message date specified by the sender organisation in the XEVPRM to which the acknowledgement message refers to.
E.8	transmissionacknowledgmentcode	Xs:string (2)	1:1	The general acknowledgement for the XEVPRM: **01**= All data (medicinal product entities) loaded into database **02** = EVPRM Error, not all data loaded into the database, check section B **03**= Serious Error, no data extracted or loaded from message
E.9	parsingerrormessage	xs:string	0:1	This data element contains the description of the problem when an error has occurred during the XEVPRM parsing process. The data element is mandatory when the transmission acknowledgment code is 03.
G	reportacknowledgment		0:N	The report (medicinal product entry) acknowledgement This section contains information the acknowledgment for each report attached to the XEVPRM.
G.1	reportname	xs:string (60)	1:1	This data element refers to the report section of the XEVPRM.

Data element reference	Data element name	Type	Cardinality	Data element description
G.2	localnumber	xs:string (60)	0:1	This data element reflects the local number assigned by the sender organisation to identify the report in the XML file. The local number may be Null for all operation types other than 'Insert' and is mandatory for the operation type 'Insert'.
G.3	EV_code	xs:string (60)	0:1	The reference to the EV_CODE assigned by the XEVMPD. May be Null if the operation type 'Insert' is unsuccessful.
G.4	operationtype	xs:nonNegativeInteger value<7	1:1	This data element refers to the Operation Type requested: 1 = Insert 2 = Update 3 = Variation *(From 16 June 2014 this operation type is no longer available in EVWEB, Gateway users, who will submit an XEVPRM containing an authorised medicinal product assigned with this operation type will receive a negative XEVPRM acknowledgement as the entire XEVPRM will be rejected).* 4 = Nullify 5 = Change Ownership *(From 16 June 2014 this operation type is no longer available).* 6 = Invalidate MA
G.5	operationresult	xs:nonNegativeInteger	1:1	The outcome of the Operation for a particular section is referenced.
G.6	operationresultdesc	xs:string	1:1	The description of the outcome of the operation.

Data element reference	Data element name	Type	Cardinality	Data element description
G.7	reportcomments		0:1	The report comment section This section contains the list of elements containing entities that were remapped by the EMA.
G.7.1	reportcomment		0:1	The parsing process will add a specific comment for each remapping.
G.7.1.1	severity	xs:nonNegativeInteger	0:1	The severity flag describes if the parsing error is flagged as an error or a warning.
G.7.1.2	sectionname	xs:string (60)	0:1	The XEVPRM section reference to which the comment is referring.
G.7.1.3	fieldname	xs:string (60)	0:1	This data element contains the field name(s) in which the remapped value appeared
G.7.1.4a	fieldvalue	xs:string	0:1	This data element contains the field value of the data element which was remapped.
G.7.1.4b	substitutedvalue	xs:string	0:1	This field contains the value substituted for the value in fieldvalue (G.7.1.4a)
G.7.1.5	commentcode	xs:nonNegativeInteger (3)	0:1	This data element contains a comment code about the remapping.
G.7.1.6	commenttext	xs:string	0:1	This data element contains a detailed explanation of the remapping.

2. Element Acknowledgement Codes

Element Acknowledgement Codes can be found on the Agency's Guidance documents related to data submission for authorised medicines webpage in the 'Controlled vocabularies' section.

3. Examples of acknowledgements

3.1. XEVPRM_ACK

```
<?xml version="1.0" encoding="UTF-16"?>
- <evprmack
xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  - <ichicsrmessageheader>
      <messagetype>EVPRACK</messagetype>
      <messageformatversion>1.0</messageformatversion>
      <messageformatrelease>1.0</messageformatrelease>
      <messagenumb>EU-EC-M-137260-ACK</messagenumb>
      <messagesenderidentifier>EVHUMAN</messagesenderidentifier>
      <messagereceiveridentifier>XXXXX</messagereceiveridentifier>
      <messagedateformat>204</messagedateformat>
      <messagedate>20150929155505</messagedate>
    </ichicsrmessageheader>
  - <acknowledgment>
    - <messageacknowledgment>
        <evmessagenumb>EU-EC-M-137260</evmessagenumb>
        <originalmessagenumb>AMP X insert_PRD111081 update</originalmessagenumb>
        <originalmessagesenderidentifier>XXXXX</originalmessagesenderidentifier>
        <originalmessagereceiveridentifier>EVHUMAN</originalmessagereceiveridentifier>
        <originalmessagedateformat>204</originalmessagedateformat>
        <originalmessagedate>20150929155342</originalmessagedate>
        <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
      </messageacknowledgment>
    - <reportacknowledgment>
        <reportname>AUTHORISEDPRODUCT</reportname>
        <localnumber>1</localnumber>
        <ev_code>PRD115953</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 PRD115953 Version [Version Number] / [Date
          and Time]".</operationresultdesc>
      </reportacknowledgment>
    - <reportacknowledgment>
        <reportname>AUTHORISEDPRODUCT</reportname>
        <localnumber/>
        <ev_code>PRD111081</ev_code>
        <operationtype>2</operationtype>
        <operationresult>4</operationresult>
        <operationresultdesc>Entity updated successfully Version 7 Please note that your product data
          is awaiting revalidation by the EMA, when this is completed you will receive a further
          acknowledgement with the message number: "Product Validated PRD111081 Version
          [Version Number] / [Date and Time]".</operationresultdesc>
      </reportacknowledgment>
    </acknowledgment>
</evprmack>
```

3.2. Additional (3rd level) XEVPRM_ACK

3.2.1. No changes were performed by the EMA as part of the AMP validation

```
<?xml version="1.0" encoding="UTF-16"?>
- <evprmack
xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  - <ichicsrmessageheader>
      <messagetype>EVPRACK</messagetype>
      <messageformatversion>1.0</messageformatversion>
      <messageformatrelease>1.0</messageformatrelease>
      <messagenumb>Product Validated as submitted PRD329691 Version 6 / 2015/10/02
        11:37:32</messagenumb>
      <messagesenderidentifier>EVHUMAN</messagesenderidentifier>
      <messagereceiveridentifier>XXXXX</messagereceiveridentifier>
      <messagedateformat>204</messagedateformat>
      <messagedate>20151002113732</messagedate>
    </ichicsrmessageheader>
  - <acknowledgment>
    - <messageacknowledgment>
        <evmessagenumb>1683511</evmessagenumb>
        <originalmessagenumb>PRD329691 Version 6</originalmessagenumb>
        <originalmessagesenderidentifier>XXXXX</originalmessagesenderidentifier>
        <originalmessagereceiveridentifier>EVHUMAN</originalmessagereceiveridentifier>
        <originalmessagedateformat>204</originalmessagedateformat>
        <originalmessagedate>20141006141650</originalmessagedate>
        <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
      </messageacknowledgment>
    - <reportacknowledgment>
        <reportname>AUTHORISEDPRODUCT</reportname>
        <localnumber/>
        <ev_code>PRD329691</ev_code>
        <operationtype>9</operationtype>
        <operationresult>601</operationresult>
        <operationresultdesc>Product validated successfully as
          submitted.</operationresultdesc>
      </reportacknowledgment>
    </acknowledgment>
</evprmack>
```

3.2.2. Changes were performed by the EMA as part of the AMP validation

```
<?xml version="1.0" encoding="UTF-16"?>
- <evprmack
xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  - <ichicsrmessageheader>
      <messagetype>EVPRACK</messagetype>
      <messageformatversion>1.0</messageformatversion>
      <messageformatrelease>1.0</messageformatrelease>
      <messagenumb>Product validated following EMA edit of data PRD116098 Version 2 /
        2015/10/13 17:02:06</messagenumb>
      <messagesenderidentifier>EVTEST</messagesenderidentifier>
      <messagereceiveridentifier>XXXXX</messagereceiveridentifier>
      <messagedateformat>204</messagedateformat>
      <messagedate>20151013170204</messagedate>
    </ichicsrmessageheader>
  - <acknowledgment>
    - <messageacknowledgment>
        <evmessagenumb>EU-EC-M-137432</evmessagenumb>
        <originalmessagenumb>EMA edit of data PRD116098 Version 1</originalmessagenumb>
        <originalmessagesenderidentifier>EVTESTWT</originalmessagesenderidentifier>
        <originalmessagereceiveridentifier>EVTEST</originalmessagereceiveridentifier>
        <originalmessagedateformat>204</originalmessagedateformat>
        <originalmessagedate>20151013165926</originalmessagedate>
        <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
      </messageacknowledgment>
    - <reportacknowledgment>
        <reportname>AUTHORISEDPRODUCT</reportname>
        <localnumber/>
        <ev_code>PRD116098</ev_code>
        <operationtype>2</operationtype>
        <operationresult>4</operationresult>
        <operationresultdesc>Entity updated successfully Version 2 Product validated
          following EMA edit of data. Please note that your product data was not deemed
          valid as submitted and was edited as part of the validation process as follows:
          Product Versions Changes Section: Presentation # Changed: Product Short
          Name</operationresultdesc>
      </reportacknowledgment>
    </acknowledgment>
</evprmack>
```

3.3. Rejected XEVPRM_ACK

```
<?xml version="1.0" encoding="UTF-16"?>
- <evprmack
xsi:noNamespaceSchemaLocation="http://eudravigilance.ema.europa.eu/schema/ACKXEVMPD.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  - <ichicsrmessageheader>
      <messagetype>EVPRACK</messagetype>
      <messageformatversion>1.0</messageformatversion>
      <messageformatrelease>1.0</messageformatrelease>
      <messagenumb>EU-EC-M-1474273-ACK</messagenumb>
      <messagesenderidentifier>EVHUMAN</messagesenderidentifier>
      <messagereceiveridentifier>XXXXX</messagereceiveridentifier>
      <messagedateformat>204</messagedateformat>
      <messagedate>20151006091031</messagedate>
    </ichicsrmessageheader>
  - <acknowledgment>
    - <messageacknowledgment>
        <evmessagenumb>EU-EC-M-1474273</evmessagenumb>
        <originalmessagenumb>PRD1169970_update</originalmessagenumb>
        <originalmessagesenderidentifier>XXXXX</originalmessagesenderidentifier>
        <originalmessagereceiveridentifier>EVHUMAN</originalmessagereceiveridentifier>
        <originalmessagedateformat>204</originalmessagedateformat>
        <originalmessagedate>20151006090822</originalmessagedate>
        <transmissionacknowledgmentcode>01</transmissionacknowledgmentcode>
      </messageacknowledgment>
    - <reportacknowledgment>
        <reportname>AUTHORISEDPRODUCT</reportname>
        <localnumber/>
        <ev_code>PRD1169970</ev_code>
        <operationtype>2</operationtype>
        <operationresult>600</operationresult>
        <operationresultdesc>Version 5 Please note that your product data is deemed not valid
          as submitted because it matches a previous version of the product that was
          edited by EMA in order to be validated.</operationresultdesc>
      </reportacknowledgment>
    </acknowledgment>
</evprmack>
```

3.4. ACK received where remapping has taken place

This section is related to the remapping of Proposed Pharmaceutical Dose Forms (PDFs) and Routes of Administration (RsoA) to Standard PDFs/ RsoA by the EMA.

Table 1. Use of the reports comments section at the reference entity level

Description	Currently used 6 fields	Report comment fields
Insert a new Administration Route (ADR) which is unique	reportname: adminroute localnumber: as submitted evcode: as assigned operationtype: 1 operationresult: 2 operationresdesc; entity	Absent

Description	Currently used 6 fields	Report comment fields
	inserted successfully	
Insert a new ADR which matches an existing current Administration Route	reportname: adminroute localnumber: as submitted evcode: ADR1234 operationtype: 1 operationresult: 2 operationresdesc: entity inserted successfully	present: severity: 2 sectionname:adminroute fieldname: name_admroute fieldvalue: value submitted substitutedvalue: ADR1234 commentcode: 22 commenttext: The value specified is a duplicate of ADR1234. This ev code was substituted and message processing continued.
Insert of a new ADR which matches a nullified ADR where there is no known duplicate available	reportname: adminroute localnumber: as submitted evcode: as assigned operationtype: 1 operationresult: 2 operationresdesc: entity inserted successfully	Absent
Insert of a new ADR which matches a nullified ADR where there is a known duplicate available	reportname: adminroute localnumber: as submitted evcode: ADR54321 operationtype: 1 operationresult: 2 operationresdesc: entity inserted successfully	present: severity: 2 sectionname: adminroute fieldname: name_admroute fieldvalue: value submitted substitutedvalue: ADR54321 commentcode: 24 commenttext: The value specified is a known duplicate of ADR54321. This ev code was substituted and message processing continued.

Table 2. Use of the reports comments section at the product level

Ref	Description	Currently used 6 fields	Report comment fields
1	Insert/update a product referencing a new ADR (contained in the same messages) which is unique	As now	Absent
2	Insert/update a product referencing a new ADR which matches an existing current ADR (from 2 or 4 in table 1 above)	As now	Absent
3	Insert/update/ MAH invalidation of a product which references an ADR by EV Code and which is a nullified ADR where there is NO known duplicate available	reportname: XXXPRODUCT[1] localnumber: as submitted if insert evcode: as submitted if update / MAH invalidate operationtype: 1/2/6 operationresult: 5/6/7 operationresdesc: Impossible to find[2]….	Absent
4	Insert/update/ MAH invalidation of a product which references an ADR by EV Code and which is a nullified ADR where there IS A known duplicate available	reportname: XXXPRODUCT[3] localnumber: as submitted if insert evcode: as submitted if update / MAH invalidate operationtype: 1/2/6 operationresult: <successful operationresdesc: Entity <operation type>[4] successfully	present: severity: 2 sectionname: adminroute fieldname: admroutecode fieldvalue: value submitted substitutedvalue: ADR54321 commentcode: 24 commenttext: The value specified is a known duplicate of ADR54321. This EV Code was substituted and message processing continued.

To which entities is remapping applied?

From 16 June 2014 the remapping is applied when attempting to insert the following reference entities. Prior to this date the entire message was rejected with an 02 acknowledgement:

[1] Where XXX is either DEVELOPMENT or AUTHORISED.
[2] The operation result description and operation result depend on the original message type.
[3] Where XXX is either DEVELOPMENT or AUTHORISED.
[4] Inserted, updated etc. as appropriate

- Pharmaceutical Forms - using the name_pharmform field (ST.PF.5)
- Routes of Administration using the name_admroute field (ST.AR.5)

To which entities is remapping applied at the product level?

From 16 June 2014[5] the remapping is applied within product fields when referencing EV Codes. This has the effect that for product operations the EMA would not load the value supplied within the product but rather the preferred identified duplicate.

Prior to June 16th 2014 when a user referenced a nullified entity the product was rejected and the acknowledgement informed the user that the referenced EV Code cannot be found.

This mapping applies to all fields which reference a pharmaceutical form EV Code or administration route EV code.

[5] Prior to this date these scenarios will all result in the rejection of the product concerned.