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Contents

Ennov InSight XEVMPD

Ennov InSight XEVMPD is designed to support a standardized and structured method of collecting, reporting, coding, and evaluating authorised medicinal product data. You can then use this data to submit medicinal product information to the European Medicines Agency (EMA).

The Ennov InSight XEVMPD module enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (XEVMPD) directive.

Your organization can use Ennov InSight XEVMPD to gather the data needed for submission in an XML file, which is referred to as the Extended EudraVigilance Product Report Message (XEVPRM). You can then create a `.zip` file that includes the XML content and electronic files of required attachments referenced in the XML file to transmit to the EudraVigilance system.

With the XEVMPD license, you can also access the XEVMPD Submissions - QC Verification and XEVMPD Submissions and Acknowledgements query reports. For more information, see *Submission Planning and Tracking Queries* in the Ennov InSight Registrations online help.

XEVMPD Wizards

In Ennov InSight , XEVMPD Wizards help you to create or update XEVMPD data.
Wizards presents you with a sequence of dialog boxes that lead you through a series of well-defined steps.

There are two wizards that enable you to perform file creation and update functions:

— *XEVMPD Submission* Wizard
— *XEVMPD Acknowledgement* Wizard

XEVMPD Submission Wizard

The *XEVMPD Submission* Wizard enables you to collect data and files from the database to include in XEVMPD submissions, and to generate `.zip` files that include the collected data and attachment files to submit to the European Medicines Agency (EMA).

The XEVMPD Submission wizard can be invoked from the Ennov InSight *Home* Page menu bar or from the *Create a New - XEVMPD Submission* section in the *I Am Looking To* pane. The wizard is available only for users with XEVMPD License, RPT (Registration Planning and Tracking), and Product Detail Management (PDM) with at least `Write` permissions, Data Administration rights set to `Yes` or `NO` (both options are acceptable since Ennov InSight 7.3.1 release), and at least `Write` permission for the XEVMPD Wizards.

The XEVMPD Submission wizard functionality of creating XEVMPD XML file can also be done via workflows. The Ennov Client Enablement team can assist in developing the necessary workflow configuration files to meet your process needs. Please contact your Business Development Representative for more information.

Create an XEVPRM ZIP File

You can use the *XEVMPD Submission* wizard to create the XEVPRM `.zip` file for submission to the EMA.

Prerequisites

The *XEVMPD Submission* wizard is available only for users with xEVMPD license, and Write permissions for RPT (Registration Planning and Tracking), Product Detail Management (PDM), and Data Administration rights set to Yes or NO (both options are acceptable since Ennov InSight 7.3.1 release) and Write permission for *XEVMPD Wizards*.

You can access the *XEVMPD Submission* wizard from the Wizards menu or from I Am Looking To > Create New > XEVMPD Submission.

To create your XEVPRM `.zip` file:

1. Select the Wizards > XEVMPD Submission.
2. On the *Select Sender/Receiver Information* page:

a) Select a Sender (menu with active values from Data Administration > Message Sender Values).
b) Select a Receiver (menu with two predefined by system values - EVTEST and EVHUMAN).

3. Click Next.
4. On the *Authrorized Product Selection* page, select or enter the search criteria and click Next.
   Click Next to show all the authorized products without the search criteria selection.
5. Make a selection on the *Authrorized Product Search Results* page.
6. Click Next.
7. On the *Authrorized Product Attachment Results* page, see the list of attachments if exist.
8. Click Next.
9. On the *Create XEVPRM Confirmation* page, select the location where your XML file is saved.
   The system can save your file to the predefined location. If the Location for XEVMPD Submission field is set correctly during the server setup, then after selecting Next on the *Create XEVPRM Confirmation* page, the generated Submission XML file will be saved to that location. The predefined location is selected by default on the *Create XEVPRM Confirmation* page. The information about the predefined location must be included in `insight.var` file. If you need to save your file to a folder other than the default, you can change the location manually.

   This option is applicable to the following DMS repositories:
   — File System
   — Documentum

   Use Browse to chose the location. Use Clear to clear the location.

Note: *If your predefined location is other than File System and you are logging on to the DMS, you will be required to enter your DMS credentials.*

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10. Click Next.
11. On the *Create XEVPRM Summary* page:
    a) A message to confirm the generation of XEVPRM `.zip` file is displayed.
    b) Click the hyperlink to save the XEVPRM `.zip` file to your desktop.
    c) After the XEVPRM `.zip` file is saved, click Finish.
    You can now submit the XEVPRM `.zip` file to EMA.

Search Criteria Selection - Authorized Product Selection

Select the criteria for the search for future authorised product data generation.

For the authorized product, the Country and Procedure Type fields display only the European Union (EU) and European Economic Area (EEA) related values. When selecting Product Family values or selecting Product Family values in combination with Product values, only the relevant values of other entities are filtered and displayed in their respective fields.

Field	Value
Application Name	The name of the application.
Country	The European Union (EU) and European Economic Area (EEA) countries.
Date Submitted to EMA	Filter based on the date submitted to EMA.
Display Columns	Columns to select to display in the result.
EV Code	The EV code of the authorised product.
Family Name	The name of the product family.
Full Product Name	The full name of the product.
Last Updated Date	Filter based on the last updated date.
License Code	The code assigned by the regulatory agency.
MAH/Organization	The company to which a license is given to market the product.
Procedure Type	Procedure types - EU specific.
Product Name	The name of the product. ***Note:*** *The Product Name field shows only the products that are associated with the corresponding Full Product Presentation through the Package Set. If no products are associated, the Product Name column will be blank.*
Show Only New Authorised Products	Filter to display only the new authorised products or all authorised products.
Sort Order	The order to display in the result.

Search Results

The Search Results include details about the section properties you selected:

Section Property	Details
Organisation	Operation type, organisation type, address, city, region, post code, country, SME status, SME number, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments
Source	Operation type, source name, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments

Section Property	Details
Master File Location	Operation type, master file location company, department, building, street, city, state, post code, country, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments
ATC	Operation type, ATC code, ATC code description, term type, acknowledged, last updated date, date submitted to EMA, version date, and XEVMPD comments
Pharmaceutical Form	Operation type, Pharmaceutical name, term type, last updated date, date submitted to EMA, local code, EV code, previous EV code, version date, and XEVMPD comments
Route of Administration	Operation type, route of administration name, term type, last updated date, date submitted to EMA, local code, EV code, previous EV code, version date, and XEVMPD comments
Authorised Product	Operation Type, Family Name, Product Name, Application Name, Procedure Type, License Code, Country, Full Product Name, EV Code, Authorisation Status, Authorisation/Renewal Date, MAH/Organisation, Information Date, Withdrawn/Invalidated Date, Package Description. Last Updated Date, Date Submitted to EMA.

Names of sections, License Code and Full Product Name, are hyperlinks. Clicking the hyperlinks displays section data in a pop-up window. You can modify the section data in this window.

XEVMPD Submission Wizard Data Collection Features

The *XEVMPD Submission Wizard* enables you to collect data and files from the database to include in XEVMPD submissions, and to generate `.zip` files that include the collected data and attachment files to submit to the European Medicines Agency (EMA).

The following sets of features are applicable for the *XEVMPD Submission Wizard* data collection.

Full Product Presentation

Important: If any Package Set is associated to the Registration, but is not associated to the Full Product Presentation under the Registration, then the Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) Details of the parent Product Details Set are not included to the XEVMPD submission.

The following is applicable for the Full Product Presentation entity:

- Active Ingredient information or strain (for a Flu Vaccine) is displayed from the selected entity. Reference Active Ingredient or Reference Strain must have an appropriate EV_CODE in Data Administration.
- If the XEVMPD Marketing Authorisation Number and XEVMPD MAH/Organisation in the Full Product Presentation entity are populated with values, then these values are included to the appropriate section in the XML file instead of the Package Set Registration values. This feature is applicable for the Invalidate MA operation type for `Not Valid` Authorisation Status only.

— For the Authorised Product XEVMPD section, when an Application has one of the EU CP (Centralised Procedure) types (e.g. EU CP Bio) selected, you can send the XEVMPD submission specific for EEA Countries, such as Norway, Iceland, or Liechtenstein. To be included to the `.xml` file, Norway, Iceland, or Liechtenstein should be selected in the EEA Country field on the Full Product Presentation. Otherwise, the Country from the PSet (Package Set) Registration is added to the XML file.

Product Detail Set

Important: The Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) PDS Details are included in an XEVMPD submission only if Package Sets from the parent PDS are associated to the Full Product Presentation.

The following is applicable for the Product Detail Set entity:

— If you set the Use as Active Ingredient for XEVMPD field in the PDS Substance Detail to Yes, then the data from Substance Detail is added as an Active Ingredient (regardless of the selected Substance Type) to an appropriate section in the XML file. If you set this field to No, then Substance Detail is used as an Excipient or Adjuvant, depending on the selected Substance Type.

— If the Strength-related fields in the PDS Active Ingredient are populated with values, then these values are included in the appropriate section in XML file instead of Component Active Ingredient values.

— For the Authorised Product XEVMPD section: if the PDS Indication/Intended Use Detail (non-Veterinary) or PDS Species Indication Detail (Veterinary) has the same Country assigned as the Country selected for the Authorised Product, then this data is added to the appropriate section in the XML file.

Note: *For Insert and Update operation types, at least one indication should exist within an Authorised Product for all supported Product Family types. The indication data is added to the appropriate section in the XML file if: it is associated on the Product Family level, it is created in the Product Detail Set with an Approved status, and the indication country is a value from either Registration entity (Country field) or Full Product Presentation entity (EEA Country filed).*

The prior approved PDS Detail from the previous Event is taken into the XEVMPD Submission if the current PDS Detail has one of the following statuses:

— Pending Modify

— Pending Withdrawal

This rule is applicable to the following PDS Details:

— Indication/Indented Use

— Indication (under Veterinary Product Family)

— Strain

— Reference Strain

— Substance (Excipient, Adjuvant, and Substance entities used as Active Ingredient)

The PDS Details with status set to Withdrawn are not included into XEVMPD Submission.

For Package Set Detail with the Withdrawn status, the following rules apply:

— If there is a FPP with EMA Authorisation Status Code for 'Not Valid' value, the PSet is included into XEVMPD logic.
— If there is a FPP with EMA Authorisation Status Code for 'Valid' value, then PSet is not included into XEVMPD logic.

For the Indication/Intended Use (non-Veterinary Product Detail Sets), Indication (Veterinary Product Detail Sets), Active Ingredient, and Substance PDS Details when there are several identical values under different Product Detail Sets, but under the same Full Product Presentation, they are represented with a common tag in the XEVMPD XML file as one value, instead of multiple values.

Applications

The following is applicable for applications of CP (Centralised Procedure) Type:

— For the Authorised Product XEVMPD section, when the Application is of `CP Type`, the `CP number` is taken from Application Code field when the Procedure Identifier field contains no data. When the Procedure Identifier field is populated with data, the `CP number` is taken from Procedure Identifier.

The following is applicable for applications of Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) Types:

— For the Authorised Product XEVMPD section, when the Application is of `MRP` or `DCP` Type, the `MRP` or `DCP number` is taken from Application Code field when the Procedure Identifier field contains no data, with the addition of the Speciality Number field information from the *Product Detail Set Attributes* page. For example: `[Application Code][Speciality Number1]`. When the Procedure Identifier field is populated with data, the `MRP` or `DCP` number is taken from Procedure Identifier field, with the addition of the Speciality Number field information from the *Product Detail Set Attributes* page. For example: `[Procedure Identifier][Speciality Number1]` .

If there is more than one PDS with the Speciality Number field populated with data, the formula for concatenation is: [Procedure Identifier/Application Code][Speciality Number1]'-'DISTINCT [Speciality Number2]. Where DISTINCT means the value different from the [Speciality Number1]. If both Speciality Number1 and Speciality Number2 are the same values, than only Speciality Number1 is taken.

Note: *The Speciality Number field is also available in PDS for the EU Herbal and EU Homeopathic types. However, this field is not connected with the `XEVMPD XML file` for those Application Types.*

Registrations

The Package Set Registration > Legal Basis value is included in the XEVMPD Submission XML file instead of the Application > Legal Basis value, when:

— The field is populated with a value for both entities.
— The Application > Legal Basis field is not populated with a value.

Important: If the Legal Basis field in not populated for an Application or for a Registration, a warning message is displayed.

Product Detail Sets

If configured, a field named Local Route of Administration for tracking country Route of Administration on PDS level is presented on the PDS Attributes page. This field is hidden by default and can be enabled via the overrides. The Route of Administration value can be taken into an XEVMPD submission from the PDS level according to the following set of rules:

— If the Local Route of Administration value is populated on the *PDS Attributes* page and the Component associated to this PDS is also associated to the Pharmaceutical Product, then this value is taken to the XEVMPD Submission XML file.

— If the Local Route of Administration value is not populated on the *PDS Attributes* page, then the Route of Administration value is taken from the Product or Component (if more than one component exists) to the XEVMPD Submission XML file.

— If the Route of Administration value is not populated on the PDS, Product, or Component Attribute page, then a warning message stating that `Route of Administration is required` is displayed in the XEVMPD Submission wizard.

— If the Route of Administration value selected in the Local Route of Administration field does not have an EV Code assigned in the Data Administration > Product Maintenance > Route of Administration Values > Route of Administration XEVMPD Information, then a warning message stating that `Route of Administration must be submitted in the XEVPRM message` is displayed in the XEVMPD Submission wizard.

Authorised Product Attachments

Every Authorised Product section can have Attachment file data that will be submitted in the final `.zip` file.

The content of the attachment cannot be updated. Each attachment must be uniquely identified within the Attachments element by the local number or EV code. The language must be specified using the two-letter language code in the published set.

The Result Set of attachments, ready for submission, include:

— Attachment Name
— Attachment Type - Printed Product Information (PPI)
— File name
— File Type
— Attachment Version
— Attachment Language
— 2nd Attachment Language
— Attachment Link
— Local Code
— Version Date
— EV Code

The results are presented in read-only format and are not available for selection.

If there are errors related to attachments, a list of validation errors is displayed and not the attachments Result Set. The error message includes `Attachment Name` (hyperlink), `Attachment Type`, `Attachment Version`, and an `Error Message` indicating the reason for failure.

- Substances, Pharmaceutical Forms, and Route of Administrations assigned to the MA should have data for Code Term Type in Data Administration XEVMPD Information subtabs.
- Language Code and Procedure Type Code must be correctly specified.
- Make sure that the Package Set Registration contains the Package Set. If not, you will not be able to view the Active Ingredient, Excipient, Adjuvant, and Indication Intended Use information.

When the Use Rendition field is set to Yes for the Registration Attachment and the Rendition Identifier value is selected, the existed in DMS location `.pdf rendition file` will be used instead of the source file in the submission creation:

- If the source file has a rendition with the same type as selected in the Rendition Identifier drop-down list, then the rendition `.pdf file` is used during the submission creation.
- If the source value has a rendition with a different type from the one selected in the Rendition Identifier drop-down list, then during the *XEVMPD Submission* wizard execution a warning message informs you that `Rendition file has not been found`.

Attachment types:

- Registration Attachment for Authorised Product

Operation Types

The medicinal product information provided via the XEVPRM is owned by the Sender Organisation that submitted the information.

The Sendor Organisation can perform the following types of operations by sending an XEVPRM:

Operation	Description
Insert	Provide new medicinal product information via an XEVPRM.
Update	Update the content of medicinal product information previously submitted via an XEVPRM.
Nullify	Nullify medicinal product information previously submitted via an XEVPRM.
Invalidate MA	Inform about the withdrawal of an authorised medicinal product from the market via an XEVPRM. The Invalidate MA operation covers a number of scenarios including transfer of an authorised medicinal product to a third party and renewal of the MA by the same MAH.

Not all operations are available for all XEVMPD entity types. The following table presents the available XEVMPD entity types and Operation Types:

XEVMPD Entity Type/Operation Type	Insert	Update	Nullify	Invalidate MA
Authorised Product	✓	✓	✓	✓
Development Product	✓	✓	✓	N/A
Approved Substance	N/A	N/A	N/A	N/A
Attachment	✓	N/A	N/A	N/A
Master File Location	✓	✓	✓	N/A
Source	✓	✓	✓	N/A
MAH	✓	✓	✓	N/A
Sponsor	✓	✓	✓	N/A
Development Pharmaceutical Form	✓	✓	✓	N/A
Proposed Pharmaceutical Form	✓	N/A	N/A	N/A
Development Route of Administration	✓	✓	✓	N/A
Proposed Route of Administration	✓	N/A	N/A	N/A
Development ATC Code	✓	✓	✓	N/A
Proposed ATC Code	✓	✓	✓	N/A

XEVMPD Acknowledgement Wizard

The *XEVMPD Acknowledgement* wizard enables you to upload the Acknowledgement XML file, received from the EMA, to Ennov InSight . The file contains EudraVigilance (EV) codes for updating the XEVMPD values.

Note: *The file can be uploaded automatically if all the settings required for this process were configured during installation of the application server.*

The *XEVMPD Acknowledgement* wizard can be invoked from the Ennov InSight *Home* Page menu bar or from the Update - XEVMPD Acknowledgement section in the *I Am Looking To* pane. The wizard is available only for users with XEVMPD License, RPT (Registration Planning and Tracking) and Product Detail Management (PDM) with at least `Write` permissions, Data Administration rights set to `Yes` or No (both options are acceptable since Ennov InSight 7.3.1 release), and at least `Write` permission for the *XEVMPD Wizards*.

Note: *For the Registration FPP Attachment, the* Validity Declaration *field is automatically updated once the* XEVMPD Acknowledgement *wizard passes. If the Registration FPP Attachment is associated to the acknowledged Authorised Product, or the Registration FPP Attachment is created from a Registration Attachment that was previously acknowledged, the value assigned is* `Previous Copy was sent (1).`

The *XEVMPD Acknowledgement* wizard enables you to upload XEVPRM files that were exported by an external system, using the Force XEVPRM Acknowledgement Import functionality.

Note: *When a* `Message Sender` *from the* `XEVPRM` *file that you are uploading using the* Force XEVPRM Acknowledgement Import *functionality does not exist in the Ennov InSight system, then it is automatically created during the wizard execution. The* `Message Sender Name` *with a prefix* `[Inserted]` *and the* `Message Sender ID` *are added to the* Data Administration *section (*Message Sender Values *under* Other Maintenance*).*

For 3rd Acknowledgement type files only, the system automatically checks EV codes that have been entered by the EMA into the `<operationresultdesc>` tag of the XML Acknowledgement File and puts the corresponding Entity Name in braces near it in the OPERATION_RESULT_DESCRIPTION database column, if the entity with such EV code exists in the system. Otherwise, the EV code is followed by `Not Defined` in braces. For example:

- `Added: Authorised Pharmaceutical Form [PHF00010MIG { Collodion} ]`
- `Added: Authorised Pharmaceutical Form [PHF00001MIG { Not Defined } ]`

The *XEVMPD Acknowledgement* wizard enables you to automate the inactivation of registration attachments once the corresponding acknowledgment has been received.

Note: *Verify that the following value exists in the* `insight.var` *file:* `xevmpd.message.import.inactivate.attachment=true`.

Acknowledgement File

Use the acknowledgement file to summarize medicinal product entry information required for future processing and authorization.

The Acknowledgement file consists of a message header and an acknowledgement report. The message header displays information that identifies the acknowledgement message.

The acknowledgement presents two sections:

- Message Acknowledgement: Summarizes findings on the message sent to the EMA for processing the medicinal product submitted for authorisation.
- Report Acknowledgement: Summarizes the results of the operation type (such as Insert, Update, Nulify, or Invalidate MA) requested for each medicinal product entry in an XEVPRM. It contains the mapping between the Local Code and the EV Codes.

Validation

The *Search Results Wizard* page displays the results included in the acknowledgement file. The results are described and the proper codes are assigned to them. The codes can be assigned to the message header and to the entities listed in the acknowledgement report.

The codes assigned to the message header:
— transmissionacknowledgmentcode = 01: All reports included in the XEVPRM file were successfully processed.
— transmissionacknowledgmentcode = 02: XEVPRM error. Not all information was successfully loaded in the database. These errors are listed in the Report Acknowledgement of the XEVPRM_Ack file.
— transmissionacknowledgmentcode = 03: Serious errors prevent the data from being loaded into the database.

Errors can occur due to:
— XML structure
— Schema validation
— Non-compliance with the business rules specified by the EMA

When an error occurs, the acknowledgement contains no data, it only contains the error message. The proper EV codes, submission, or acknowledgement entries are not updated in the database.

Upload XEVPRM XML File

After you have received the acknowledgement file from the EMA, upload it to Ennov InSight . The acknowledgement file contains EV codes for updating the XEVMPD values.

Prerequisites

The *XEVMPD Acknowledgement* wizard is available only for users with:
— xEVMPD license
— Write permissions for RPT (Registration Planning and Tracking) and *XEVMPD Wizards*.
— Product Details Management (PDM) and Data Administration rights set to Yes or No (both options are acceptable since Ennov InSight 7.3.1 release).

To upload an XEVPRM XML File:

1. From the Wizards menu or from I Am Looking To > Create New, open *XEVMPD Acknowledgement* wizard.
2. On the *Import XEVPRM Acknowledgement XML* page, select the output location.
3. Click Browse and select the XML file.
4. On the *Verify XEVPRM Acknowledgement XML* page, the wizard verifies the correspondence of the imported XML file and the system, in which it was generated.
5. Click Next
6. On the *Force XEVPRM Acknowledgement Import* page, the following messages are displayed:

System Message	Description
`No input is required on this page`	This message appears if the submission file for the selected acknowledgment file was created using the Ennov InSight system.

System Message	Description
`XEVPRM was not exported from this system. Would you like to run Force Acknowledgement Import?`	This message appears if the submission file for the selected acknowledgment file was created using the external system. The values available for selection in the Force Import field are Yes and No.

On the *Import XEVPRM Acknowledgement Results* page, the import results appear with file details (entities that are successfully uploaded and errors, if any, occurred) are displayed. If Yes was selected, in addition to import results, the Imported by Force information appears with the number of imported entities.

7. Save the XML file on your desktop.
   On the subsequent page, Success or Failure codes are included in the XML file.

2nd Acknowledgement Type File

The 2nd Acknowledgement Type File helps to identify the Acknowledgement message.

The 2nd Acknowledgement type file includes:

`Message Header`: Contains information to identify the Acknowledgement message.

`Acknowledgement`: Consists of multiple sections:

— `Section A` is a message acknowledgement, and summarizes the EMA findings on the message sent to EMA for processing medicinal product submitted for authorization.

— `Section B` is the acknowledgement report. This report summarizes the results of the operation type (such as Insert, Update, or Nullify) requested for each medicinal product entry in an XEVPRM.

The name of the acknowledgement file should be presented in the following format: `'ack_'+<file name sent by the user>`.

3rd Acknowledgement Type File

The 3rd acknowledgement type is used to identify changes made by EMA during the QC process for authorised products only.

The 3rd Acknowledgement type file includes:

— Message Header: contains information to identify the Acknowledgement message.

— Acknowledgement: consists of multiple sections (described in the following table).

The number of received Acknowledgements depends on the number of sections in one submission message. You receive one 3rd acknowledgement file per one submitted section.

	EMA performed no changes	EMA performed changes
Section A	Section A is a message acknowledgment, summarizes the EMA findings on the 3rd Acknowledgment message type. Possible results: — If all reports was successfully processed you will see `transmissionacknowledgementsode = 1` — Message number contains `Product validated as submitted + <EV Code> + Version + <Validated Version Number> + / + <Date and Time>` — Original message number contains `<EV Code> + Version + <Version Number>` — Original message date contains `<Validated Date and Time>`	Section A is a message acknowledgment, summarizes the EMA findings on the 3rd Acknowledgment message type. Possible results: — If all reports was successfully processed you will see `transmissionacknowledgementsode = 1` — Message number contains `Product validated following EMA edit of data + <EV Code> + Version + <Validated Version Number> + / + <Date and Time>` — Original message number contains `EMA edit of data + <EV Code> + Version + <Version Number used as based for the Changes>` — Original message date contains `<Validated Date and Time>`
Section B	Section B is the acknowledgement report. This report summarizes the results of the validation made for each authorized medicinal product entry. Possible results: — Operation type is `9` — Operation result is `601` — Operation result description: `Product validated successfully as submitted`	Section B is the acknowledgement report that summarizes the results of the EMA updates performed. Possible results: — Operation type is `2` — Operation result is `4` — Operation result description `Entity updated successfully Version + <Assigned Version Number> + <Provided product version changes>`
File Name	`Validated + - + <Sender ID of the Validated Version> + - + <EV Code> + - + <Validated Version Number> + - + <Date and Time> + .xml`	`ackval + _ + <EV Code> + _ + <New Version Number> + .xml`

XEVMPD Acknowledgement Report Codes

Numbered codes that appear in the Acknowledgement Report can be Success Codes or Failure Codes. Those success and failure codes are described in the following tables.

Only the first error encountered is reported in the Acknowledgement Report.

For all elements and operations except product operations, any failure code results in the entire message being rejected with the 03 transmission acknowledgement code. Failures generated by product operations generate the 02 transmission acknowledgement code. In this case, all operation results will be reported in the acknowledgement.

Table 1: Success Codes

Operation Result Code	Text in Acknowledgement
2	The entity was inserted successfully.
3	The entity was nullified successfully.
4	The entity was updated successfully.
29	The entity was withdrawn, or the MA was invalidated successfully.

Table 2: Failure Codes

Operation Result Code	Text in Acknowledgement
1	The entity is already presented in the EVMPD. You need to use the EV Code specified in the acknowledgement.
5	Impossible to find the specified EV Code.
6	Impossible to find a referred entity. You need to check the specified foreign keys.
7	Impossible to find a referred entity. You need to check the specified foreign keys.
8	The requested operation does not exist.
9	The requested operation is not implemented.
10	Security Error. Insufficient Rights. You need to check the Ownership of the specified entity.
12	Missing Mandatory Information.
13	Unsuccessful Insert. You need to contact the EMA Help Desk.
14	Unsuccessful Update. You need to contact the EMA Help Desk.
15	Unsuccessful Nullify. You need to contact the EMA Help Desk.
16	Security Error. Impossible to update a private entry owned by another Organisation.

Operation Result Code	Text in Acknowledgement
17	Impossible to add the substance, a specified name is already present in the EVMPD.
18	Referred entity(EV_CODE) could not be found.
19	You need to contact the EMA Help Desk.
20	General Error. You need to contact the EMA Help Desk.
21	Security Error. The sender Organisation is not registered with EV system.
23	Impossible to find a referred entity. You need to check the specified foreign keys.
24	The entity is referred to by others entities: Nullification not allowed.
25	Ambiguous EV Code. You need to contact the EMA Help Desk.
26	Version Date specified is not valid.
27	Standard Term Type Error. There is a more recent term (Proposed or Standard) in the EVMPD.
28	Only Authorised Products can be withdrawn.
30	Unsuccessful Withdrawn Generic Error. You need to contact the EMA Help Desk.
70	Error in the Product indication referred by the Product.
71	Sponsor data supplied matches *<EV CODE>* within the xEVMPD. Please use *<EV CODE>* or correct the submitted data.
73	Update of preferred name of substance *<EVCODE>* is forbidden. If the name is a synonym of *<current preferred name>*, you need to add the new name as an alias for *<EVCODE>*. If *<new name>* is a different substance to *<original name>*, you need to enter a new substance with your preferred name. If the original name contains an error, you need to contact the EMA.
76	Only the EMA may update products where the authorisation status is within the not valid authorisation status sub-list. If your product is in this status in error, you need to contact the EMA to request a correction.
77	If the value of authorisation status is `Valid – Transferred Marketing Authorisation` or `Valid – Renewed Marketing Authorisation` of MA then the Previous EV Codes section must be present.
78	If the value of authorisation status is `Valid – Transferred Marketing Authorisation` or `Valid – Renewed Marketing Authorisation` then at least one Previous EV Code section must reference the EV Code of a current authorised product.

Operation Result Code	Text in Acknowledgement
79	If the operation type is withdrawal or Invalidate MA, the authorisation status must be one of the values in the published Not Valid Authorisation Status.
80	If the operation type is Insert, Update or Variation then the authorisation status must be one of the values from the published valid authorisation status.
81	If the value of authorisation status does not signify a current valid MA then WithdrawnDate must be present.
82	If the value of authorisation status signifies a current valid MA then WithdrawnDate must be empty.
83	The EMA is not currently accepting updates to proposed Pharmaceutical Forms and Routes of Administration standard terms. You need to check that the term you have used does not exist and if necessary add a new proposed term.
85	The EMA is not currently accepting nullifications of proposed Pharmaceutical Forms and Routes of Administration standard terms.
99	The code idicates the Parsing error(s).
500	SME status field must be absent for Sponsor organisation.
501	SME status field must be present for current MAH organisation.
502	SME number field value prohibited with SME status field value provided.
503	MAH data supplied matches *<EV CODE>* within the XEVMPD. You need to use *<EV CODE>* or correct the submitted data.
504	At least 1 authorised pharmaceutical form is mandatory for this operation type.
505	Where multiple authorised pharmaceutical forms are specified each must be unique, code *<duplicated code>* is duplicated.
506	Referenced local pharmaceutical form (local ref:*<localref>*) not found or is a development term.
507	Referenced global pharmaceutical form (*<EVCode>*) not found or is a development term.
508	The legal basis is mandatory for this operation type.
509	The value of the legal basis field is not in the list of permitted values.
510	Authorisation country must be in EEA if an EU authorisation procedure is specified.
511	At least 1 medicinal product type is mandatory for this operation type.
512	Where multiple medicinal product types are specified each must be unique, code *<duplicated code>* is duplicated.

Operation Result Code	Text in Acknowledgement
513	The value *<unmatched value>* in the medicinal product type field is not in the list of permitted values.

XEVMPD Error Message for Authorised Product

The following table lists the Authorised Product error messages and their description.

Error Message	Description
Validity Declaration on Registration FPP Attachment entity is required to be with value for submission.	This error occurs when there is no value in the Validity Declaration field for the selected Registration FPP Attachment entity.
At least one Registered ATC must be selected on Registration entity.	This error occurs when there is no ATC assigned to the Registration entity.
Qualified Person for Pharmacovigilance (QPPV) is required for this operation type.	This error occurs when there is no value in the QPPV field on Registration entity.
QPPV name should be valid (positive integer).	This error occurs when there is no value in the QPPV field on Registration entity.
Short Name must be specified.	This error occurs when there is no value in the Short Name field for the selected FPP entity.
Short Name must not exceed 250 characters.	This error occurs when there are more than 250 characters in the Short Name field for the selected FPP entity.
Withdrawn/Invalidated Date must be specified to Invalidate MA the authorised product.	This error occurs when there is no date specified in the Withdrawn/Invalidated Date field for the selected FPP entity.
XEVMPD Comments must be specified on FPP entity for Invalidate MA operation of Authorised Product.	This error occurs when there is no value in the XEVMPD Comment field for the selected FPP entity.
Procedure Type is required.	This error occurs when there is no procedure type for the selected Application entity. This error also occurs if an incorrect value is entered for the Procedure Type Code in DA.
At least one Indication is required for this operation type.	This error occurs when there is a no Indications/Intended Use PDS Detail created.

Error Message	Description
MedDRA Code is required to submit indication data.	This error occurs when there is no value in the MedDRA Code field in DA for the created Indications/Intended Use PDS Detail.
MedDRA Level in Data Administration is required to submit indication data.	This error occurs when there is no value in the MedDRA Level field in DA for the created Indications/Intended Use PDS Detail.
MedDRA Term version is required to submit indication data.	This error occurs when there is no value in the MedDRA Term Version field in DA for the created Indications/ Intended Use PDS Detail.
Authorisation Status on FPP entity is required to be with value for this Operation Type.	This error occurs when there is no value in the Authorisation Status field for the selected FPP entity and Operation Type in the Wizard.
Authorisation Number cannot exceed 100 characters.	This error occurs when there are more than 100 characters in the License Code field for the Registration entity.
Authorisation/Renewal Date on FPP entity is required to be with value for this Operation Type.	This error occurs when there is no Authorisation/Renewal Date field for the selected FPP entity.
MRP Number is required for this procedure type.	This error occurs when there is no value for the condition Application Code or the Application Identifier and PDS->Speciality Number (CP only).
Orphan Drug on Application entity is required to be with value for selected Operation Type.	This error occurs when there is no value in the Orphan Drug field for the Application entity.
Withdrawn/Invalidated Date is required for this operation type.	This error occurs when there is no value in the Withdrawn/ Invalidated Date field for the selected FPP entity.
Withdrawn/Invalidated Date must be empty if Authorisation Status is valid MA.	This error occurs when there is no value in the Withdrawn/ Invalidated Date field for the selected FPP entity.
Withdrawn/Invalidated Date is required to be with value for this status type.	This error occurs when there is no value in the Withdrawn/ Invalidated Date field for the selected FPP entity.
The operation type must be Invalidate MA for this status type.	This error occurs when an invalid value is selected for the Authorisation Status field for the selected FPP.
The operation type cannot be Invalidate MA for this status type.	This error occurs when an invalid value is selected for the Authorisation Status field for the selected FPP.

Error Message	Description
If the Operation Type is Insert, Update or Invalidate MA then Legal Basis on Registration or Application entity must be specified.	This error occurs when the Operation Type is Insert, Update or Invalidate MA and there is no value for the Legal Basis field on Registration or Application entity.
If the Operation Type is not Nullify then at least one Medicinal Product Type must be specified.	This error occurs when the Operation Type is not Nullify and there is no value for the Medicinal Product Type on Registration entity.
If the Operation Type is not Nullify then at least one Authorised Pharmaceutical Form must be specified.	This error occurs when the Operation Type is not Nullify and there is no value for the Authorised Pharmaceutical Form on FPP entity.
This Authorised Pharmaceutical Form must be submitted in this message.	This error occurs when there is no value in the Authorised Pharmaceutical Form field on FPP entity.
This Authorised Pharmaceutical Form must not represent a Development Pharmaceutical Form.	This error occurs when the Authorised Pharmaceutical Form selected on FPP entity has a Development Term in Dosage/ Pharmaceutical Form Values in DA.
If the Operation Type is Insert or Update and Authorised Pharmaceutical Form has XEVMPD Code then Authorised Pharmaceutical Form must represent a Standard or Proposed Pharmaceutical Form.	This error occurs when the Authorised Pharmaceutical Form selected on FPP entity does not have a EV Code or Standard Term, or Proposed Term in Dosage/Pharmaceutical Form Values in DA.
Product INN/Common Name on FPP entity is required to be with value.	This error occurs when there is no value in the Product INN/ Common Name field for the selected FPP entity.
Product INN/Common Name cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product INN/Common Name field for the selected FPP entity.
Company Name on FPP entity is required to be with value.	This error occurs when there is no value in the Company Name field for the selected FPP entity.
Company Name cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Company Name field for the selected FPP entity.
Product Strength cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product Strength field for the selected FPP entity.
Product Form cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product Form field for the selected FPP entity.
Package Description cannot exceed 2000 characters.	This error occurs when there are more than 2000 characters in the Package Description field for the selected FPP entity.

Error Message	Description
MFL on Registration entity is required to be with value for selected Operation Type.	This error occurs when there is no value for the MFL field on Registration entity.
The Master File Location must be submitted in this message.	This error occurs when there is no value in the MFL field on Registration entity.
Registration Attachment EV Code is required for submission.	This error occurs when there is no value in the EV Code field on Registration Attachment entity.
This substance can be used only once within Pharmaceutical Product.	This error occurs when a same substance is selected as AI and Excipient/Adjuvant.
The Marketing Authorisation Holder must be submitted in this message.	This error occurs when MAH/Organisation selected on Registration entity does not have a EV Code or MAH Code in MAH/Development Sponsor/Organisation Values in DA.
No Marketing Authorisation Holder was specified.	This error occurs when there is no value for the MAH/ Organisation field on Registration entity.
Pharmacovigilance Enquiry Email is required for this operation type.	This error occurs when there is no value in the Enquiry Email field on Registration entity.
Pharmacovigilance Enquiry Phone Number is required for this operation type.	This error occurs when there is no value in the Enquiry Phone Number field on Registration entity.
No valid Pharmaceutical Products were found. At least one Pharmaceutical Product with Active Ingredient measure information must be specified.	This error occurs when there is no Pharmaceutical Product created.
No Active Ingredients were specified.	This error occurs when Substance selected as Active Ingredient (Reference AI/Reference Strain/PDS AI) entity does not have a EV Code or Approved in Substance Values in DA.
High Amount Numerator Value must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Numerator Unit must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for the selected Non-Range Concentration Type.

Error Message	Description
High Amount Numerator Prefix must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator Prefix field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for the selected Non-Range Concentration Type.
High Amount Denominator Value must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Denominator Unit must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator Unit field on Component Product AI/ Reference AI or on PDS AI (Reference Strain/Excipient/ Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Denominator Prefix must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator Prefix field on Component Product AI/ Reference AI or on PDS AI (Reference Strain/Excipient/ Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Numerator Unit must match Low Amount Numerator Unit.	This error occurs when the value in the High Amount Numerator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Numerator Unit field for the same entity.
High Amount Denominator Unit must match Low Amount Denominator Unit.	This error occurs when the value in the High Amount Denominator Unit field on Component Product AI/ Reference AI or on PDS AI (Reference Strain/Excipient/ Adjuvant) entity is different to the value of the Low Amount Denominator Unit field for the same entity.
High Amount Denominator Prefix must match Low Amount Denominator Prefix.	This error occurs when the value in the High Amount Denominator Prefix field on Component Product AI/ Reference AI or on PDS AI (Reference Strain/Excipient/ Adjuvant) entity is different to the value of the Low Amount Denominator Prefix field for the same entity.
High Amount Denominator Value must match Low Amount Denominator Value.	This error occurs when the value in the High Amount Denominator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Denominator field for the same entity.

Error Message	Description
Concentration Measure Type Code is required.	This error occurs when there is no value for the Concentration Measure Type Code field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Numerator Value is required.	This error occurs when there is no value for the Low Amount Numerator field on PDS AI (Reference Strain/Excipient/ Adjuvant) entity.
Low Amount Numerator Prefix is required.	This error occurs when there is no value for the Low Amount Numerator Prefix field on PDS AI (Reference Strain/ Excipient/Adjuvant) entity.
Low Amount Numerator Unit is required.	This error occurs when there is no value for the Low Amount Numerator Unit field on PDS AI (Reference Strain/Excipient/ Adjuvant) entity.
Low Amount Denominator Value is required.	This error occurs when there is no value for the Low Amount Denominator field on PDS AI (Reference Strain/Excipient/ Adjuvant) entity.
Low Amount Denominator Prefix is required.	This error occurs when there is no value for the Low Amount Denominator Prefix field on PDS AI (Reference Strain/ Excipient/Adjuvant) entity.
Low Amount Denominator Unit is required.	This error occurs when there is no value for the Low Amount Denominator Unit field on PDS AI (Reference Strain/ Excipient/Adjuvant) entity.

Auto Upload and Process Acknowledgement Files

Ennov InSight provides you with the ability to select an acknowledgement file to execute using the wizard, or to upload the file automatically. However, these actions can be performed only if the required settings are configured during the application server installation.

Acknowledgement Wizard

Make sure that:

1. Location for XEVMPD Acknowledgement file has correct path to the folder *<Folder Name >*, which contains an additional folder with the name `processed` for the files that are already uploaded by the system.
2. Defined Interval field has the number in minutes that corresponds to the time period for the system to check this folder for files.
3. XEVMPD Acknowledgement Force Import field, for acknowledgement files that have related submission files that were created outside of the Ennov InSight system, is set to Yes. The default value is set to No.

When the file is uploaded by the system automatically, you can receive an alert in Alert Center about the processed file. You also can receive the details via email notification or by using both email and Alert Center functions.

A message appears in the Notes section of the System Alert to indicate that files have been imported using the Force XEVPRM Acknowledgement Import functionality.

Import Result Information	
Import Result:	EMA Acknowledgement file Ack_Insert_Update_all.xml was processed
Acknowledgement Message Name:	Ack_Insert_Update_all.xml
Acknowledgement Message Date:	11-Nov-2015
Acknowledgement Message Type:	2
Entities Acknowledged:	
Organisations:	0
Sources:	1 AMIS
Attachments:	0
Master File Locations:	0
Pharmaceutical Forms:	0
Routes of Administration:	0
ATCs:	0
Authorised Products:	0
Notes:	Acknowledgement file has been uploaded using Force Import functionality;
	See Reports for more information.

Note: *To receive notifications regarding auto uploaded XML acknowledgement files, you must create an XEVMPD Import Result notification first.*

If the acknowledgement file that is imported by Force XEVPRM Acknowledgement Import functionality has an EV Code identical to any already existing in the Ennov InSight system, the number of imported entities is displayed in the result table in the *System Alert* and *XEVMPD Acknowledgement Wizard Import XEVPRM Acknowledgement Result* page.

If you have configured acknowledgement file upload automatically through the application server setup, you do not need to execute the wizard manually because all required actions will be performed by the system.

Submission Wizard

The system can show the predefined location path on the *Create XEVPRM Confirmation* page if the settings were configured during application server installation:

— The Location for XEVMPD Submission field should have the correct path to the folder `<Folder Name >`, where the system will put the created ZIP file.

XEVMPD Data Administration Sections Correspondence

As a data administrator, you are responsible for setting up and maintaining the data available in selection lists in Ennov InSight .

The following tables represent the different Data Administration section groupings in correspondence to XEVMPD (Extended EudraVigilance Medicinal Product Dictionary).

Table 3: Application Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Procedure Type Values	✓

Table 4: Other

Data Administration Section Groupings/Functionalities	XEVMPD
Concentration Measure Type Values	✓
Denominator Unit Values	✓
Indications/Intended Use Values	✓
Language Values	✓
Legal Basis Values	✓
MAH/Development Sponsor/Organization Values	✓
Master File Location (MFL) Values	✓
Message Sender Values	✓
Numerator Unit Values	✓
Previous EV Code Values	✓
SME Status Values	✓
Unit of Measure Prefix Values	✓

Table 5: Product Detail Set Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Compendial Designation/Source Values	✓
Substance Role Values	✓
Manufacturer Values	✓

Data Administration Section Groupings/Functionalities	XEVMPD
Substance Type Values	✓

Table 6: Product Family Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
ATC Values	✓
Substance Attachment Values	✓
Substance Class Values	✓
Substance Values	✓

Table 7: Product Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Dosage/Pharmaceutical Form Values	✓
Medical Device Values	✓
Route of Administration Values	✓

Table 8: Registration Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
EMA Authorization Status Values	✓
Medicinal Product Type Values	✓
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	✓

XEVMPD Entities

The XEVMPD Entities are Ennov InSight entities, which take part in XEVMPD processes.

The full list of entities:

— Product Families
— Products
— Components
— Pharmaceutical Product
— Component Active Ingredient
— Reference Active Ingredient for Component Active Ingredient
— Applications
— Events
— Product Detail Sets (PDS)
— Package Set Registration
— Full Product Presentation
— FPP Previous EV Code
— Registration FPP Attachment
— Registration Attachment

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