Calyx RIM for XEVMPD

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Contents

Calyx RIM for XEVMPD **1**
XEVMPD Wizards 1
XEVMPD Submission Wizard 1
Wizard Navigation 1
Search Criteria Selection 3
Search Criteria Selection - Authorised Product Selection 4
Search Results 5
XEVMPD Submission Wizard Data Collection Features 6
Authorised Product Attachments 9
Creating an XEVPRM ZIP File 10
Operation Types 12
XEVMPD Acknowledgement Wizard 13
Navigation 14
Acknowledgement File 15
Validation 15
Uploading an XEVMPD Acknowledgement File 16
Upload Your XEVPRM XML File 16
2nd Acknowledgement Type File 17
3rd Acknowledgement Type File 17
XEVMPD Acknowledgement Report Codes 19
XEVMPD Error Messages for Authorised Product 22
Auto Upload and Process Acknowledgement Files 27
XEVMPD Data Administration Sections Correspondence 28
XEVMPD Entities 30
SPOR Integration 30
Retrieving the RMS Data 32
Retrieving the OMS Data 33

Index **34**

Calyx RIM for XEVMPD

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

Calyx RIM for 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).

Your organisation can use Calyx RIM for 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.

XEVMPD Wizards

In Calyx RIM, 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 Calyx RIM *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`, 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 Calyx 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.

Wizard Navigation

Use the Next and Back buttons at the bottom of the page to navigate within the Wizard. Clicking the Back button in your Web browser does not always return you to the previously viewed page in the *XEVMPD Submission*

Wizard. Instead, a page farther back in the wizard structure may appear, requiring you to use the Next button to return to the appropriate page.

The *XEVMPD Submission* wizard consists of:
— Select Sender/Receiver Information
— Select XEVPRM Sections:Search Criteria Selection, Search Results
— Create XEVPRM Confirmation
— Create XEVPRM Summary

The following sections are available for selection:

Section	Description
Organisation	Select either Marketing Authorisation Holder (MAH) and/or Sponsor to be included in the XML file.
Source	Select the Compendial Designations that will be included in the XML file.
Master File Location (MFL)	Choose which Master File Locations you want to include in the XML file.
ATC	Anatomical Therapeutic Chemical. Select the ATC codes that will be included in the XML file.
Pharmaceutical Form	Select the Dosage/Pharmaceutical forms that will be included in the XML file.
Route of Administration	Choose the Route of Administration that will be included in the XML file.
Authorised Product	Choose the Authorised Products that will be included in the XML file.

There are sections that can be sent to EMA independently, and sections that can be sent in a set with other sections:

Section	Description
Organisation (MAH, Sponsor)	Independent from other sections.
Source	Independent from other sections
Master File Location (MFL)	Independent from other sections.
ATC (Development ATC Code, Proposed ATC Code)	Independent from other sections.
Pharmaceutical Form (Development Pharmaceutical Form, Proposed Pharmaceutical Form)	Independent from other sections.
Route of Administration (Development Route of Administration, Proposed Route of Administration)	Independent from other sections.

Section	Description
Authorised Product	Independent from other sections, or in a set with the all other sections.
Attachment	Only in a set with an Authorised Product.

If the operation type is changed from `Update` to `Nullify` and you perform the sort, entities with operation type `Nullify` are omitted and are not included in the sorting.

The *Create XEVPRM Confirmation* page enables you to choose the location where your XML file will be saved.

Note: *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 chosen 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 works for the following DMS repositories:
— File System
— Livelink
— Documentum
— SharePoint

You still can change the location using Browse button or clear the location with Clear button.

Note: *If your predefined location is other than File System and you are logging on to the DMS, then you will see a pop-up message prompting you to enter your credentials.*

Search Criteria Selection

Search Criteria Selection enables you to choose the criteria for the search.

Common search criteria for different section properties:

Search Criteria	Description
Show only new...	For all section properties.
... Name (text entry field)	For all section properties, except Master File Location, ATC, and Authorised Product.
Last Updated Date	For all section properties, except Authorised Product.
Date Submitted to EMA	For all section properties, except Authorised Product.

Search Criteria	Description
Display Columns	For all section properties.
Sort Order	For all section properties.
Country	For Master File Location and Authorised Product only.

Search criteria, individual for section properties:

Search Criteria	Description
Master File Location Company (text entry field)	For Master File Location only.
ATC Code Description (text entry field)	For ATC only.
MAHs	For Authorised Product only.
Procedure Type	For Authorised Product only.
Full Product Name	For Authorised Product only.

Search Criteria Selection - Authorised Product Selection

Search Criteria Selection enables you to choose the Authorised Product criteria for the search.

When the ***Authorised Product*** section is selected, then 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
Product Family Name	The name of the product family.
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 via Package Set. If no products are associated, the Product Name column will be blank.*
Procedure Type	Procedure types - EU specific.
Application Name	The name of the application.
Country	The European Union (EU) and European Economic Area (EEA) countries.
License Code	The code assigned by the regulatory agency.

Field	Value
MAH/Organisation	The company to which a license is given to market the product.
Full Product Name	The full name of the product.
EV Code	The EV code of the authorised product.
Show Only New Authorised Products	Filter to display only the new authorised products or all authorised products.
Last Updated Date	Filter based on the last updated date.
Date Submitted to EMA	Filter based on the date submitted to EMA.
Display Columns	Columns to select to display in the result.
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
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

Section Property	Details
Authorised Product	Operation Type, Product 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:

- If you set the Use Reference Ingredient for XEVMPD field in the Full Product Presentation entity to Yes, you will see the reference active ingredient or reference strain data (for a Flu Vaccine) in an appropriate section in the XML file. If you need to include active ingredient information or strain (for a Flu Vaccine), the field should be set to No. 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:

— Active Ingredient (including the Reference Active Ingredient logic)
— 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
— 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, the attachments Result Set is not displayed. You will see the list of validation errors. 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.

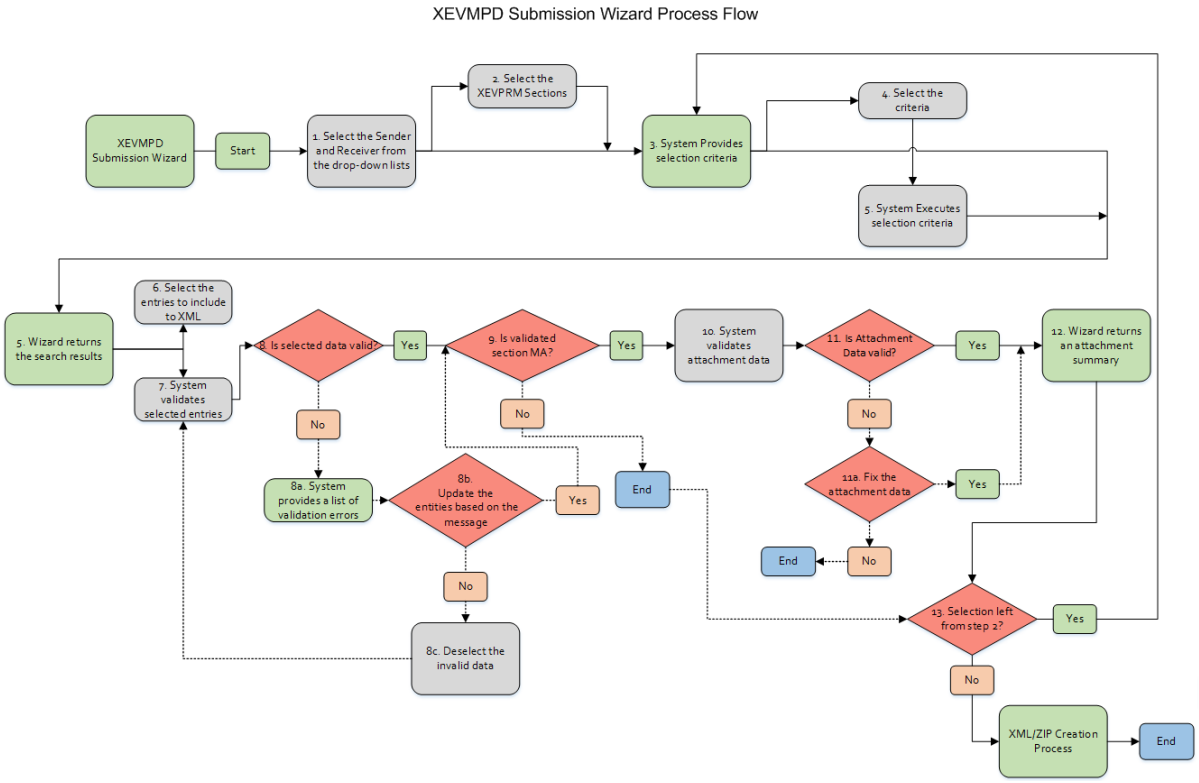
When the Use Rendition field is set to Yes for the Registration Attachment and the Rendition Identifier value is selected, the existed in DMS location `.pdf rendition file` will be used instead of the source file in the submission creation:

— 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

Creating an XEVPRM ZIP File

You can use the *XEVMPD Submission Wizard* to create the XEVPRM `.zip` file for submission to the EMA. The *XEVMPD Submission* wizard can be invoked from the Calyx RIM *Home Page* menu bar or from the Create a New - XEVMPD Submission section in the *I Am Looking To* pane. You can also use *XEVMPD Submission* wizard functionality of creating XEVMPD XML file via workflows.



Use the following procedure to create your XEVPRM `.zip` file:

1. Choose WIZARDS > XEVMPD Submission (or Create a New - XEVMPD Submission).

2. On the *Select Sender/Receiver Information* page:
   a) Select a Sender (drop-down menu with `Active Message Sender Name Values` from Data Administration).

      The Authorised Product section is filtered by Sender value. The value is automatically filled by the system with the Full Product Presentation entity Message Sender field the first time it is used in the wizard. Values with a blank Message Sender field, and Marketing Authorisation values with the Sender field selected in the Full Product Presentation entity, are available when you select the Authorised Product section.
   b) Select a Receiver (drop down menu with two predefined by system values - `EVTEST` and `EVHUMAN`).
3. To proceed, click Next.
4. On the *Select XEVPRM Sections* page, select one or more of the available XEVMPD sections:
   — Organisation
   — Source
   — Master File Location
   — ATC
   — Pharmaceutical Form
   — Route of Administration
   — Authorised Product

   If there are validation errors associated with your selected XEVPRM Sections, the system displays messages describing the errors.
5. To proceed, click Next.
6. Do the following:
   a) Specify search criteria for the selected XEVPRM properties.

      Depending on the XEVPRM properties selected, additional filters may appear for defining your search.
   b) The wizard guides you through criteria selection according to the XEVPRM properties you selected.

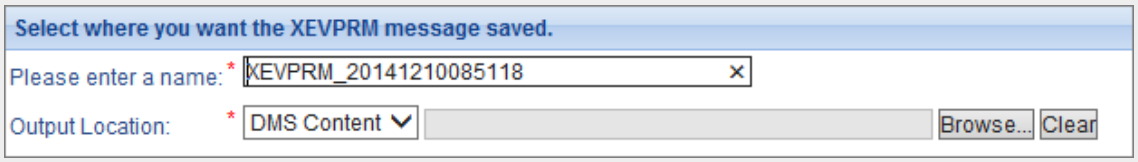
      Display Columns is the only required search criteria field for all section properties. All other criteria are optional.
7. To proceed, click Next.
8. On the *Search Results* page:
   — Organisation name, Source name, Master File Location Company, ATC Code, Pharmaceutical Form name, Route of Administration name, and Authorisation Number are hyperlinks. You can click on the name and modify the data in the pop-up window.
   — The columns can be sorted, refreshed, and exported to Excel.
   — You can correct the errors by clicking on the hyperlinked name of the section and correct the fields that resulted in validation errors. After correcting the field, refresh the pop-up window. If there are errors with Attached data for Authorised Product, you need to exit the wizard and fix the data.
9. To proceed, click Next.
10. On the *Create XEVPRM Confirmation* page:
    a) Please enter a name: You can accept the system-generated name in this field, or enter a new name for XEVPRM message to be saved.

In the following image, `XEVPRM_20141210085118` is a system-generated name.

Warning: Avoid using special characters in the **name** *field, such as: \ or / or &*

b) **Output location**: Specify the location where the message will be saved. Select the document management system or file share from the list and browse to choose the specific location in your system. Select the location, and then click **OK**.

Example



Note: *The system has an ability to automatically save a file to a predefined location during the server setup, then after selecting* **Next** *button on the* **Create XEVPRM Confirmation** *screen generated Submission XML file will be saved to that location. You can change the location using the* **Browse** *button. If your predefined location is other than File System and you are logging on to a DMS, a pop-up message will prompt you to enter your credentials.*

11. To proceed click **Next**.
12. On the ***Create XEVPRM Summary*** page:
    a) You can see the confirmation that the XEVPRM `.zip` file was generated successfully.
    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.

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.

Operation	Description
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	✓	✓	✓	✓
Attachment	✓			
Master File Location	✓	✓	✓	
Source	✓	✓	✓	
MAH	✓	✓	✓	
Sponsor	✓	✓	✓	
Development Pharmaceutical Form	✓	✓	✓	
Proposed Pharmaceutical Form	✓			
Development Route of Administration	✓	✓	✓	
Proposed Route of Administration	✓			
Development ATC Code	✓	✓	✓	
Proposed ATC Code	✓	✓	✓	

XEVMPD Acknowledgement Wizard

The *XEVMPD Acknowledgement* wizard enables you to upload the Acknowledgement XML file, received from the EMA, to Calyx RIM. 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 Calyx RIM *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`, 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 Calyx RIM 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`.

Navigation

The following buttons enable you to navigate through the wizard when you invoke the wizard manually:

Button	Description
Next	Proceed to the next page of the wizard.
Back	Return to the previous page of the wizard. All changes that you made on the current page persist.
Finish	Initiates the import process. The data is loaded to the database. If the data loaded successfully, you see the Confirmation Message. If errors occurred, the Error Message appears with the description of unresolved issues that prevent data from being loaded.
Cancel	Cancel all previous actions. As a result no updates are made to the database.

If the file is uploaded automatically through the application server setup, you do not need to invoke the wizard. All necessary actions are performed by the system. You will receive the notification about the process via Alert Center on the Calyx RIM *Home* Page or via the email message. The system displays all details including the error messages related to acknowledgement file.

Note: *You can get more details on submission and acknowledgement files using the Reports functionality.*

The following information should be presented in the `config.file` to ensure that the acknowledgement XML File auto uploads correctly:

— Location for XEVMPD Acknowledgement: The location from which the file will be uploaded.
— Defined interval (minutes): The interval in minutes shows how often the system will check the updates made by EMA in your acknowledgement XML file.
— XEVMPD Acknowledgement Force Import: For acknowledgement files with related submission files that were created outside of the Calyx RIM system. Values available for selection are Yes and No. The default value is set to `No`. To automatically upload the XEVPRM files that were exported by an external system, select Yes.

Acknowledgement File

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.

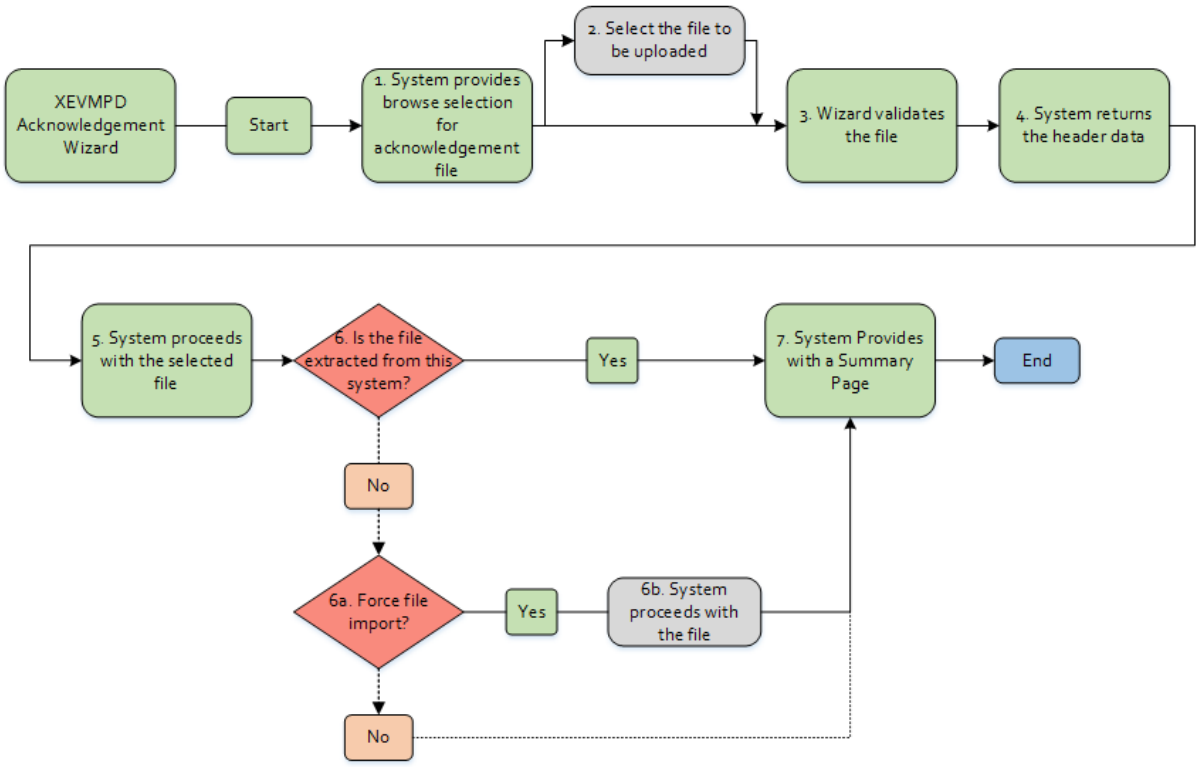
Uploading an XEVMPD Acknowledgement File

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

The ***XEVMPD Acknowledgement Wizard*** can be invoked from the Calyx RIM ***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, at least `Write` permissions for RPT (Registration Planning and Tracking), Data Administration rights set to `Yes`, and at least `Write` permission for ***XEVMPD*** Wizards.

The Import XEVPRM Acknowledgement XML process consists of the following stages:
— Import XEVPRM Acknowledgement XML
— Verify XEVPRM Acknowledgement XML
— Force XEVPRM Acknowledgement Import
— Import XEVPRM Acknowledgement Results.

Upload Your XEVPRM XML File



1. Choose WIZARDS > XEVMPD Acknowledgement (or Update - XEVMPD Acknowledgment).

2. On the *Import XEVPRM Acknowledgement XML* page, choose the output location of your file. Click Browse and select the XML file.
3. 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. To proceed click Next.
4. On the *Force XEVPRM Acknowledgement Import* page:
   — If the submission file for the selected acknowledgement file has been created using the Calyx RIM system, the following is stated: `1. No input is required on this page.`
   — If the submission file for the selected acknowledgement file has been created using the external system, the following is stated: `XEVPRM was not exported from this system. Would you like to run Force Acknowledgement Import?` - and the values available for selection in the Force Import drop-down field are Yes and No. To upload your file, select Yes.

   On the *Import XEVPRM Acknowledgement Results* page, the results of the import are presented with the resulting information about the file (which entities were successfully uploaded and what kind of errors occurred). If Yes has been selected, in addition to import results, the Imported by Force information appears with the number of imported entities.
5. You can save the XML file on your desktop. No additional actions are needed.
   On the resulting page, you can see either Success or Failure codes that are presented in the XML file.

2nd Acknowledgement Type File

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 acknowledgment, 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 file includes:
— Message Header: contains information to identify the Acknowledgement message.
— Acknowledgement: consists of multiple sections (described in the following table).

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

The number of received Acknowledgements depends on the number of sections in one submission message.

	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`

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

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 Messages 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.
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.

Error Message	Description
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.
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.

Error Message	Description
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.
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.

Error Message	Description
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.
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.

Error Message	Description
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.
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.

Error Message	Description
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

You can execute an acknowledgement file via the ***Acknowledgement Wizard***, or you can upload the file automatically depending on the application server configuration.

Calyx RIM 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 the correct path to the folder `<Folder Name >`, which contains an additional folder named `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 Calyx RIM 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.

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 Calyx RIM 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.

Note: *When actions are invoked by a SYSMAINT user, the details of the user that performs the auto upload functionality using Calyx RIM will not be recorded in the XEVMPD Audit Report.*

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 Calyx RIM.

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	✓

Data Administration Section Groupings/Functionalities	XEVMPD
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	✓
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 Calyx RIM 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

SPOR Integration

To support the integration with EMA OMS and RMS API, and to enable adding the controlled vocabulary for organisations and referentials data from the external system, Calyx RIM provides the ability to enable and configure the SPOR services.

To start receiving data from the EMA SPOR REST Server, the options described in both the Configuration and Authentication sections must be set in the `insightConfig.bat` or `insight.var` file.

Configuration

The SPOR services can be enabled and configured through the appropriate options in the `insightConfig.bat` or `insight.var` files:

Table 9: `insightConfig.bat`

Under the `SPOR API Settings` section, values for the `Enable SPOR API RMS`, `Enable SPOR API OMS` and `Defined Interval (minutes)` options must be set.	By default, the `Enable SPOR API RMS` and `Enable SPOR API OMS` options are set to false and the `Defined Interval (minutes)` option is not populated with a value: — `Enable SPOR API for RMS: false` — `Enable SPOR API for OMS: false` — `Defined Interval (minutes):` If you set the `Enable SPOR API for RMS` option to `true`, then the RMS data will be retrieved according to the rules described in the *Retrieving the RMS Data* topic. If you set the `Enable SPOR API for OMS` option to `true`, then the OMS data will be retrieved according to the rules described in the *Retrieving the OMS Data* topic.

Table 10: `insight.var`

Under the `SPOR API SETTINGS` section, values for the `spor.api.enable.rms`, `spor.api.enable.oms` and `spor.api.update.interval.minutes` options must be set.	By default, the `spor.api.enable.rms`, `spor.api.enable.oms`, and the `spor.api.update.interval.minutes` option are not populated with a value: — `spor.api.enable.rms=` — `spor.api.enable.oms=` — `spor.api.update.interval.minutes=` The acceptable values for the `spor.api.enable.rms` and `spor.api.enable.oms` are `true` or `false`. If you set the `spor.api.enable.rms` option to `true`, then the RMS data will be retrieved according to the rules described in the *Retrieving the RMS Data* topic. If you set the `spor.api.enable.oms` option to `true`, then the OMS data will be retrieved according to the rules described in the *Retrieving the RMS Data* topic.

Authentication

To enable the authentication between the Calyx RIM system and the SPOR API client, Calyx RIM provides the ability to configure the authentication mechanism through the appropriate options in the `insightConfig.bat` or `insight.var` files:

Table 11: `insightConfig.bat`

Under the `SPOR API Settings` section, values for the `User Name` and `Password` options must be set.	By default, both options appear blank: — `User Name:` — `Password:`

Table 12: `insight.var`

Under the `SPOR API SETTINGS` section, values for the `spor.api.user` and `spor.api.password` options must be set.	By default, both options appear blank: — `spor.api.user=` — `spor.api.password=`

Retrieving the RMS Data

The uniqueness of the values in any SPOR-related tables in the Data Administration > SPOR Maintenance section is defined by the concatenation of Term Name and Term Identifier values. This concatenation must be unique within SPOR RMS list.

When the configurations are completed in the `insightConfig.bat` or `insight.var` files, the values from the EMA SPOR REST Server are loaded to the corresponding tables in the Calyx RIM Data Administration > SPOR Maintenance section:

— ATC RMS Values
— Compendial Designation/Source RMS Values
— Concentration Measure Type RMS Values
— Country RMS Values
— Denominator/Numerator Unit RMS Values
— Dosage/Pharmaceutical Form RMS Values
— EMA Authorisation Status RMS Values
— Language RMS Values
— Legal Basis RMS Values
— Medical Device RMS Values
— Medicinal Product Type RMS Values
— Procedure Type RMS Values
— Route of Administration RMS Values
— Unit of Measure Prefix RMS Values

All values loaded from the EMA SPOR REST Server will have the status Inactive in Calyx RIM.

If you manually modify any loaded value, during the next loading the values are overwritten with the values from EMA SPOR REST Server.

The first loading starts in 5 minutes after all required settings are saved. The further loadings start according to the time value defined in the Defined Interval (minutes) attribute.

Important: If the started sync is not finished, but according to the set time interval the next one should be started, then it is not going to start until the previous is finished.

Retrieving the OMS Data

Important Information

In the Calyx RIM system the uniqueness of the MAH/Development Sponsor/Organisation information is determined by the EV Code value (MAH/Development Sponsor/Organisation Values > MAH/Development Sponsor XEVMPD Information), whilst in the EMA SPOR system it is determined by the Organisation Identifier value. During the synchronisation, the matching EV Code value determines the MAH/Development Sponsor/Organisation information to be added to the Calyx RIM Data Administration table. If there are more matching EV Codes in the EMA SPOR system, then the first matching information found is synchronized. The other matching entries will be listed in the Comments field in a comma delimited manner.

It is recommended to set the `enable.spor.api.oms` option in the `insight.var` file, or the `Enable SPOR API for OMS` option in the `insightConfig.bat` file, to `true` only if there are no MAH/Development Sponsor/Organisation Values in the Calyx RIM system. If many MAH/Development Sponsor/Organisation Values entries exist, it is recommenced to not retrieve data from the EMA SPOR system in order to eliminate the unnecessary structural data discrepancies.

When the configurations are completed in the `insightConfig.bat` or `insight.var` files, the values from the EMA SPOR REST Server are loaded to the corresponding tables in the Calyx RIM Data Administration > Other section:

— MAH/Development Sponsor/Organisation Values

The fields are populated according to their availability on the EMA SPOR REST Server. The MAH/Development Sponsor XEVMPD Information tab is populated for the values that are loaded from the EMA SPOR REST Server if the needed data exists in the SPOR API system. If set to `Active`, the loaded values from the MAH/Development Sponsor/Organisation Values table can be selected for Product Family and/or Registration (becomes available for selection only if the MAH Code, or Sponsor Code is populated).

All values loaded from the EMA SPOR REST Server will have the status Inactive in Calyx RIM.

If you manually modify any loaded value, during the next loading the values are overwritten with the values from EMA SPOR REST Server.

The first loading starts in 5 minutes after all required settings are saved. The further loadings start according to the time value defined in the Defined Interval (minutes) attribute.

Index

C

Common 27

D

Data Admin 28

X

XEVMPD 1, 3–6, 9, 10, 12–17, 19, 22, 30, 32, 33