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Information Management Division

Changes to some business rules of the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)

Submission of substance information

As previously communicated, in the context of improvement of the XEVMPD Substance Controlled Vocabulary data quality, the XEVMPD business rules have been revised to reject any operation type related to submission of **approved and development substances**.

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

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

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

[1] Link to the substance request form added.

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

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

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

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

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

  - If requesting that a translation is added to an approved substance entry, the translation, the applicable language and reference source information should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
  - If requesting that an alias is added to the substance entry, the alias and reference source should be included in the request.
  - Any requests containing 5 substances and more (insert and/or update) should be submitted in an Excel spreadsheet, which will then be sent back to the requestor with the assigned EV codes and/or comments where applicable.

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

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

- ***Request for an update of an approved substance*** should be stated in the request subject;
  - The translation, the applicable language information and reference source should be included in the request. For languages where the grammar uses declined forms, the nominative singular form (i.e. not declined) of the translated substance name should be provided.
  - If requesting that an alias should be added to the substance entry, the alias and reference source should be included in the request.
  - Any requests containing 5 substances and more (insert and/or update) should be submitted in an Excel spreadsheet, which will then be sent back to the requestor with the assigned EV codes and/or comments where applicable.

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

The Agency will process the requests in the XEVMPD.

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

To request a new development substance to be entered in XEVMPD in the context of a submission of a CT Application or an investigational medicinal product (IMP) submission in the xEVMPD

A search in the EUTCT or the xEVMPD is the starting point to request changes or additions to the substance data. The following options are available:

- The user locates the substance information and determines that no changes are required to the data. In such case the user continues with the completion and submission of their regulatory application.
- **If substance** data is found, but **requires an update,** or if **substance** data is **not found** and **requires registration**, the user can do the following:

  a) Download and complete the **substance request form.**

     i) Company code can be set as the substance preferred term

     ii) Privacy settings can be adjusted for all additional names and molecular formula

  b) Go to EMA Service Desk portal and create a request. In the request:

     i) Attach completed substance request form.

     ii) **Attach the supporting documentation for the substance** (e.g. SmPC or Investigator's Brochure)

c) Finalise and submit the request

- All substance requests are processed by **EMA Data Stewards**. They will validate the request upon pre-registration or update of the substance. There will be **4w/d SLA** that will be applied.
- Once the substance is registered the user will receive an **e-mail confirmation** from the EMA Service Desk that substance data has been registered or updated.
- Registered or updated **substance data** will be available for selection in the eAF, xEVMPD, IRIS, EudraCT and EudraGMDP automatically.

This process is outlined below.