Introduction to the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)

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Who submits data in XEVMPD

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XEVMPD

*Centralised **source** of information on authorised and un-authorised medicines*

Authorised medicinal **product data** is submitted and maintained in the XEVMPD by **marketing authorisation holders (MAHs)**

as per Article 57(2) of Regulation 726/2004

Un-authorised (referred to in the XEVMPD as 'development') medicinal product data is **submitted and maintained** in the XEVMPD by **sponsors**

as per Article 81(3) of Regulation (EU) No 536/2014

Substance records are submitted and maintained in the XEVMPD by EMA's **Substance Management Service (SMS) data stewards**

MAH and **sponsor organisation** records are submitted and maintained in the XEVMPD by **MAHs** and **sponsors**

Referential terms are submitted and maintained in the XEVMPD by **MAHs, sponsors** and **EMA's Referentials Management Service (RMS) data stewards**

Who submits **un-authorised** medicinal product data in XEVMPD

- **Commercial** and **non-commercial sponsors**
  - Clinical research organisations (CROs), IT vendors and third-party service providers **may be registered by a sponsor organisation** in EudraVigilance **as a third-party service provider.**
  - They **act on behalf of the sponsor organisation** by providing services related to EudraVigilance.

The EV Registration team provides additional support for **non-commercial sponsor registrations**

See section ***8. Non-Commercial Sponsors Additional Organisation & User management support*** of the EV Registration Manual

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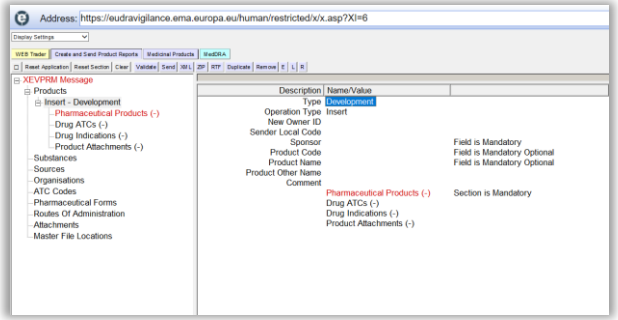
- Electronically, in an **eXtended EudraVigilance Medicinal Product Report Message (XEVPRM)**:
  - In ***XEVMPD data entry tool ('EVWEB')***
  - Submitted via EVWEB (***WebTrader*** submission mode)
    - Accessible by **registered users only**
    - Users must have **ActiveX** and **IE Tab extension** downloaded on their computers



  - Via ***application programming interface (API)*** v
    - Submitted via ***Gateway*** transmission mode

- **XEVPRM Acknowledgment (ACK)** is provided to the sender organisation **after each submission**; <u>if successful</u>, the **EV Code** assigned to the product entity **is referenced**

Submission principles: Use of active substance in a clinical trial

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If an **active substance** is used in a clinical trial in a **new pharmaceutical dose form** and/or in a **new strength,** the **sponsor submits** development medicinal product (DMP) record in the XEVMPD

Example 1:

Sponsor A studies *substance X* in the form of a *hard capsule* and as a *solution for injection*. The strength of the active ingredient in both pharmaceutical forms is *200 mg.*

Sponsor A submits 2 DMP records in the XEVMPD:

DMP 1 = *hard capsule* containing *200 mg* of *substance X*
DMP 2 = *solution for injection* containing *200 mg/ml* of *substance X*

Example 2:

Sponsor A studies *substance X* in the form of a *hard capsule* in two different strengths of the active ingredient: *200 mg* and *400 mg.*

Sponsor A submits 2 DMP records in the XEVMPD:

DMP 1 = *hard capsule* containing *200 mg* of *substance X*
DMP 2 = *hard capsule* containing *400 mg* of *substance X*

Submission principles: Use of product authorised in the EEA (1/2)

If a medicinal product **authorised in the EEA** is used in a clinical trial **as authorised** (i.e., in *the same pharmaceutical form*, with the *same active substance* and *unchanged active substance strength*), the **sponsor does not submit** a DMP in the XEVMPD

- The AMP information is submitted in the XEVMPD by the MAH

Example:

Medicinal product A is *authorised in the EEA* as a *soft capsule* containing *500 mg of substance X.*

Sponsor A uses product A in their clinical trial as it was authorised, i.e.: as a *soft capsule* containing *500 mg of substance X.*

- The **MAH** submits an authorised medicinal product (AMP) record in the XEVMPD.
- The **sponsor** does not submit a DMP record in the XEVMPD.

Submission principles: Use of product authorised in the EEA (2/2)

If a medicinal product **authorised in the EEA** is used in a clinical trial **in different composition than as it was authorised** *(i.e.: in different pharmaceutical form, different active ingredient(s) or changed active substance strength*), the **sponsor submits** a DMP record in the XEVMPD

Example:

Medicinal product A is *authorised in the EEA* as a *soft capsule* containing *500 mg of substance X.*

Sponsor A uses product A in their clinical trial but, instead of using 500 mg of substance X in a soft capsule, *500 mg of substance X* is administered as a *solution for injection.*

Sponsor A submits a DMP record in the XEVMPD:
DMP = *solution for injection* containing *500 mg/ml* of *substance X*

Submission principles: Use of product authorised outside the EEA

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If a medicinal product **authorised outside the EEA** is used in a clinical trial, the **sponsor submits** a DMP record in the XEVMPD

Example:

Medicinal product A is *authorised in Canada* as a *film-coated tablet* containing *200 mg of substance X.*

Sponsor A uses product A in their clinical trial as it is authorised in Canada, i.e.: as a *film-coated tablet* containing *200 mg of substance X.*

Sponsor A submits a DMP record in the XEVMPD:

DMP = *film-coated tablet* containing *200 mg of substance X*

Use of the same DMP by different sponsors

Since each DMP record in the XEVMPD is sponsor-specific, if **different sponsors** study the **same active substance** in the **same pharmaceutical dose form** and/or the **same strength**, **each sponsor submits** their own DMP record in the XEVMPD

Example:

Sponsor A studies *substance X* in the form of a *solution for injection;* the strength of the active ingredient is *400 mg/ml.*

Sponsor B also studies *substance X* in the form of a *solution for injection;* the strength of the active ingredient is also *400 mg/ml.*

Sponsor A submits a DMP record in the XEVMPD:
DMP = *solution for injection* containing *400 mg/ml* of *substance X*

Sponsor B submits a DMP record in the XEVMPD:
DMP = *solution for injection* containing *400 mg/ml* of *substance X*

Data visibility and confidentiality in the XEVMPD

- **DMP records** & **Investigator Brochures** are considered **confidential in XEVMPD**
- Visible in EVWEB only to:
  - Registered users from the sponsor organisation that owns that data in the XEVMPD
  - Registered EMA users
  - Registered users from national competent authorities (NCAs)

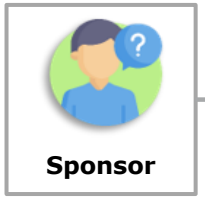
To register a trial in CTIS:

- An '**EU substance number**' and '**EU product number**' must be available in CTIS
- A search must be performed for the EU MP number **together** with the EU substance number

  (*i.e.: the EV Code of the substance **referenced as the active substance** in the medicinal product in the XEVMPD*)

- **EU substance number** = EV Code assigned to **substance record** in XEVMPD
- **EU product number** = EV Code assigned to a **product record** in XEVMPD

How to obtain **EU product number** for CTIS: **Authorised product**



Access to EVWEB

Search the XEVMPD to retrieve:

- the **EV Code of an authorised medicinal product** record and
- the **EV Code of the active substance** referenced in that AMP

No Access to EVWEB

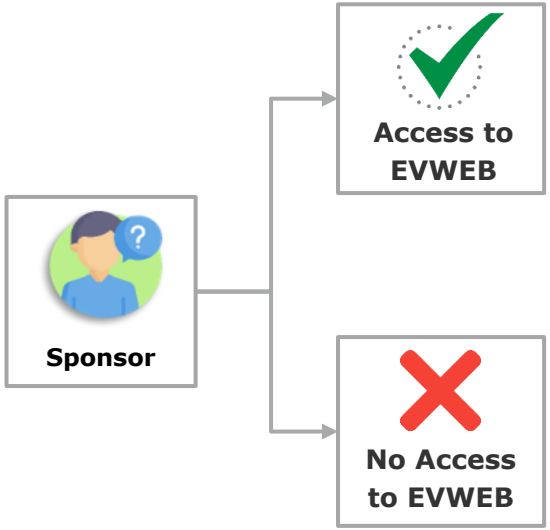
Submit an EMA Service Desk request for XEVMPD/Art.57 Services to **request the EV Codes***

The XEVMPD team performs the search based on the specified criteria and, if the product record is found, provide you with the EV Code(s)

> 5 w/d SLA

*Specify:
- name of the medicinal product (as stated in section 1 of the SmPC)
- authorisation number
- authorisation country
- name of the MAH

How to obtain **EU product number** for CTIS: **Un-authorised product**



Search the XEVMPD to retrieve:

- the **EV Code of a development medicinal product** record submitted by your organisation and
- the **EV Code of the active substance** referenced in that DMP

Check your WebTrader Inbox for the XEVPRM ACK following your DMP submission

Submit an EMA Service Desk request for XEVMPD/Art.57 Services **to request the EV Codes***

The XEVMPD team performs the search based on the specified criteria and, if the product record is found and your organisations owns that product entry, provide you with the EV Code(s)
> 5 w/d SLA

*Provide the XML of your submitted XEVPRM

How to obtain **EU substance number** for CTIS

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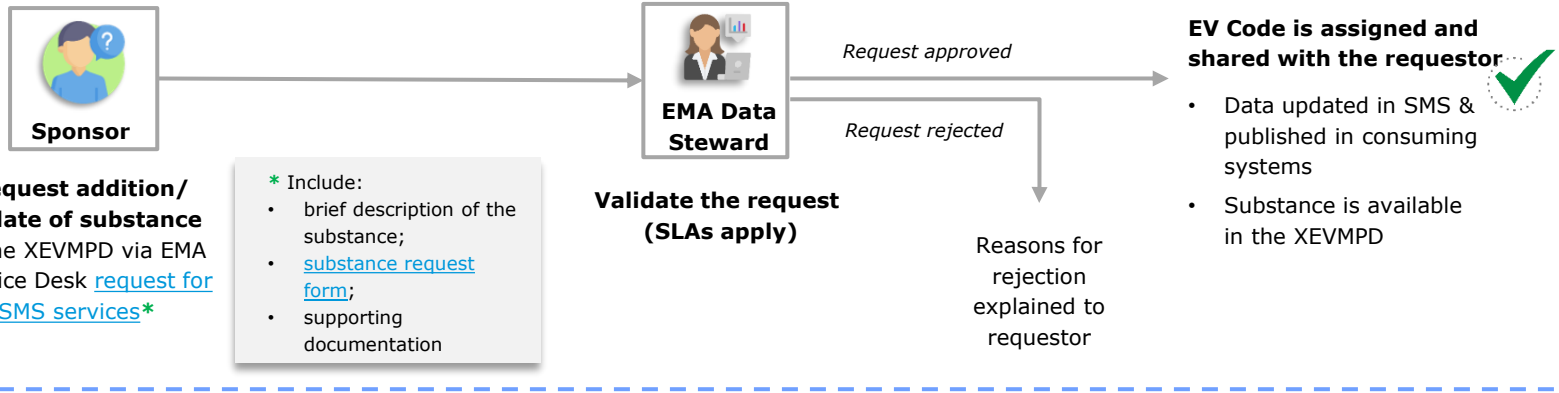
Substance available

- Sponsors **with access to EVWEB:** search in the XEVMPD substance look-up tables
- Sponsors **without access to EVWEB:** download the current/non-current substance lists from the SMS portal

Substance missing



Pre-submission requirements for non-commercial sponsors

Non-commercial **sponsor organisation** must be registered:

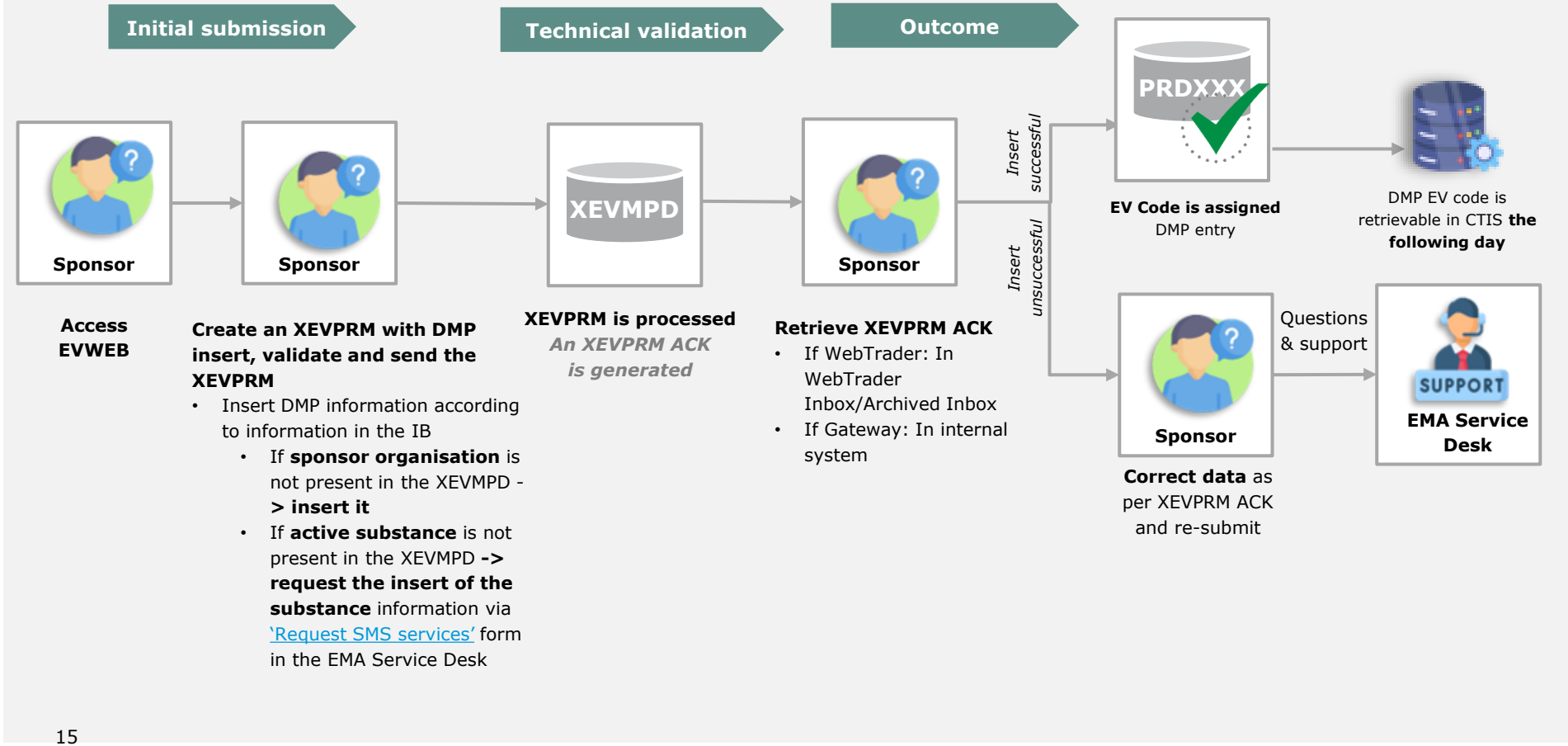
- In the Organisations Management System (OMS)
- With EudraVigilance, for **medicinal product reporting**

Non-commercial sponsor organisation **users** must be registered:

- In the EMA Account Management system
- At least one user must follow the XEVMPD training and obtain

  a *'Notification of successful completion of the XEVMPD training course'*

DMP: Initial submission process via EVWEB



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- Overview of submission requirements for sponsors
  - Guidance document
  - FAQ document

- Steps for registered users to follow to access EVWEB (incl. ActiveX installation and download of IE Tab extension)
- Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual

- Step-by-step document on how to insert a DMP in the XEVMPD

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XEVMPD support is provided via EMA Service Desk:

- To **request information**, please use the 'Ask a question' form:
  - in the 'Service' section of the form, select '**SPOR**'
  - in the 'Service Offering' section, select '**XEVMPD/Art.57**'
- To **request XEVMPD data** (e.g. an EV Code of an AMP), use the 'Request XEVMPD/Art.57 Services' form
- To **report a technical issue with XEVMPD/Art57 database or tools**, please use the 'Report an Issue with XEVMPD/Art.57' form

Further information

Contact the XEVMPD team via the **EMA Service Desk**

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to 'Ask a question' **Telephone** +31 (0) 88 781 8520

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