



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) e-learning

XEVMPPD data submission process

Version 1





XEVMPD
(aka 'Article
57 database')



**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 **EMA's Referentials Management Service (RMS) data stewards** and **sponsors (development terms only)**

AMP: Initial submission process overview

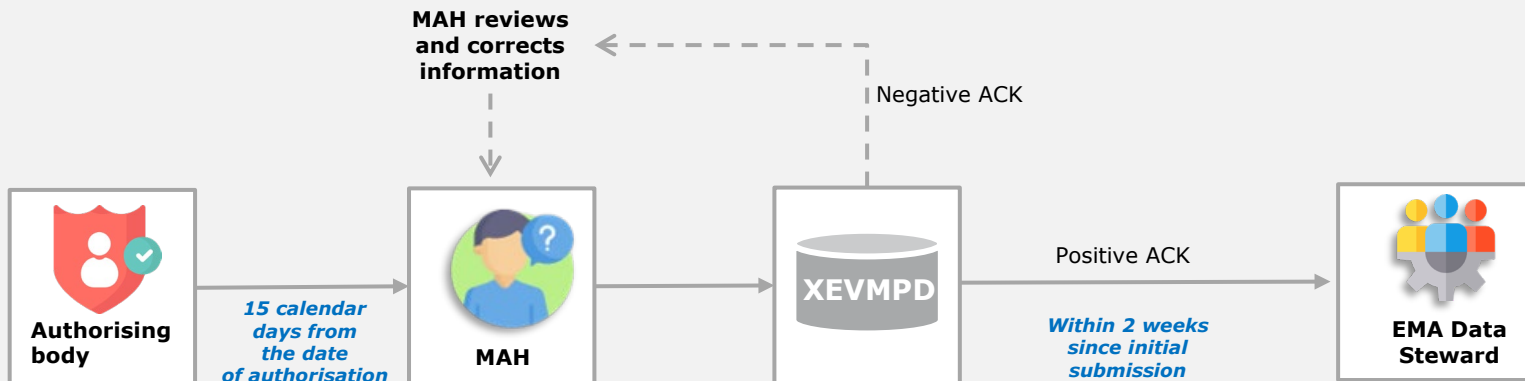


Marketing authorisation

Initial submission to Art57 database

Technical validation

Content validation/Standardisation



Marketing authorisation approval is granted

MAH submits AMP information in XEVMPD
Including MAH/PSMFL/QPPV and supporting document(s) (e.g. SmPC/PIL/Module 3 extract)

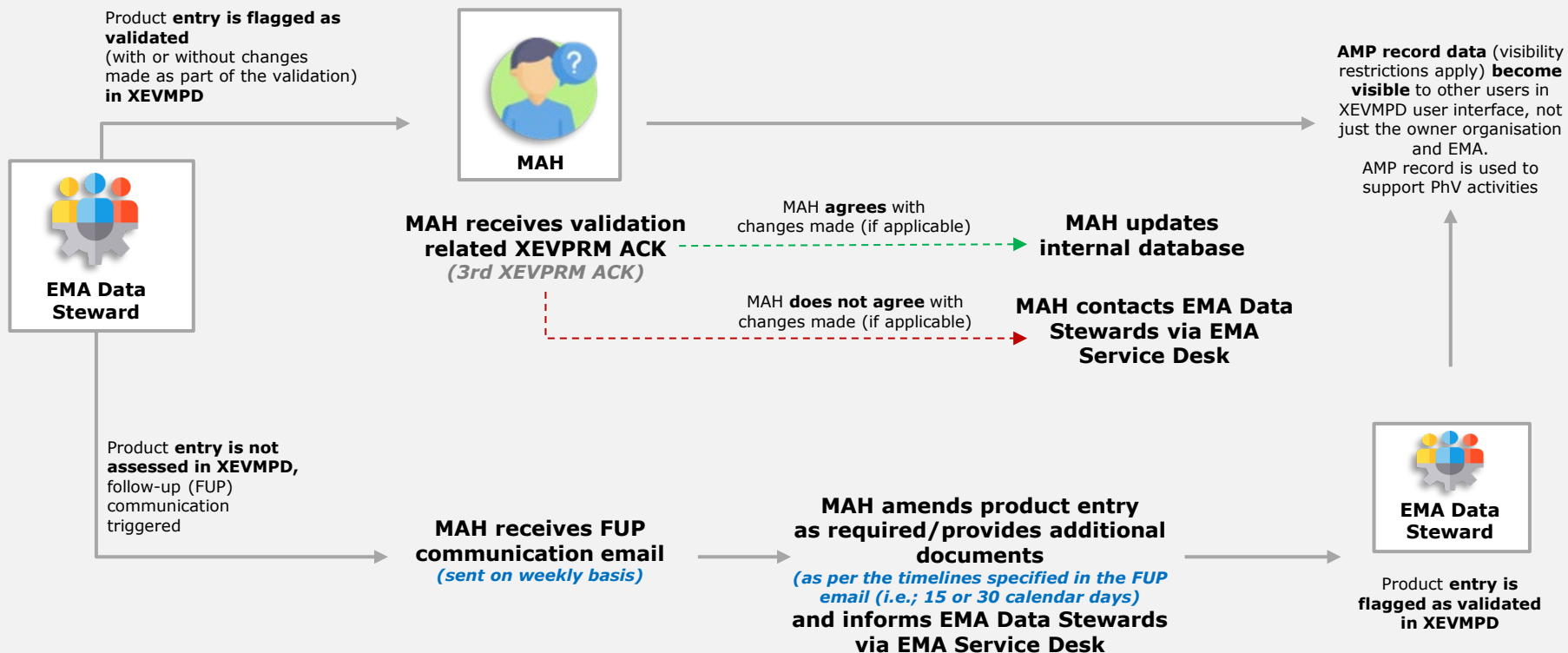
Outcome of technical validation is provided via XEVPRM Acknowledgement

1st and 2nd XEVPRM ACK (within one XML file)
Within 48 hours

Content validation is performed

- based on
- Information provided in documents
 - [Chapter 3.II](#) describing the business rules/approach for entering AMP data
 - [Data quality control methodology](#)
 - Rational assessment of the submitted information

Content validation outcome - AMP validated/flagged for FUP

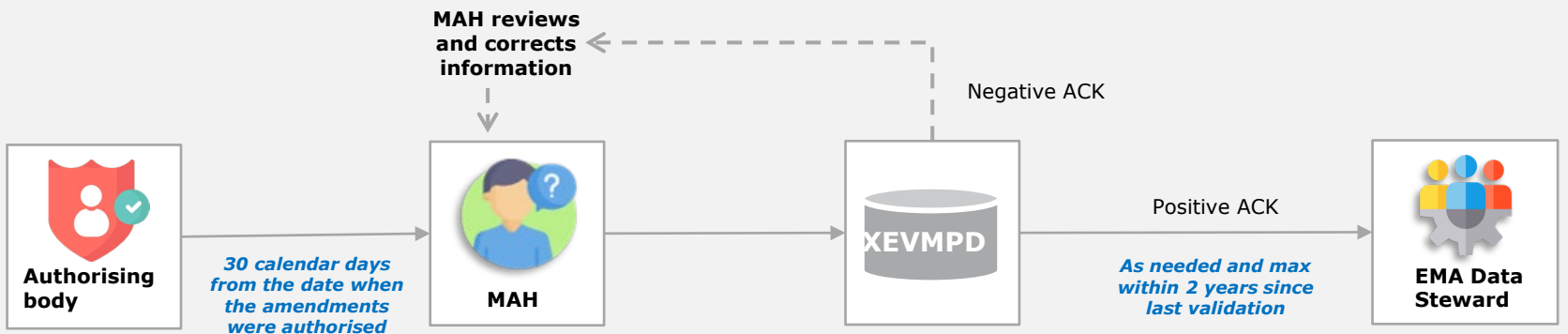


MA amendment is authorised

Data amendment in Art 57 database

Technical validation

Content validation/Standardisation



MAH inserts/updates/invalidates AMP data in XEVMPD as applicable

- Based on processes described in [Chapter 3.II](#): business guidance
- Insert and reference in the AMP record(s) **supporting document(s)**

Outcome of technical validation is provided via XEVPRM Acknowledgement

1st and 2nd XEVPRM ACK (within one XML file) Within 48 hours

Content validation is performed

Outcome of content validation is shared with MAH via 3rd XEVPRM ACK*



*Not every version of an AMP is validated

No further validation is performed on nullified or invalidated AMPs

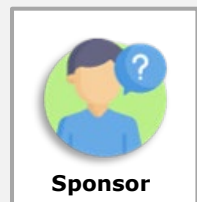
DMP: Initial submission process



Initial submission

Technical validation

Outcome



Sponsor

Enters and submits DMP data in the XEVMPD

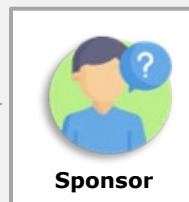
- Insert DMP information according to information in the IB



Outcome of technical validation is provided via XEVPRM Acknowledgement

1st and 2nd XEVPRM ACK (within one XML file)

Within 48 hours



Sponsor

Retrieves XEVPRM Acknowledgement

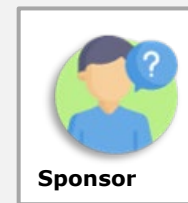
Insert successful

Insert unsuccessful



EV Code is assigned
DMP entry is **flagged as 'Valid' in XEVMPD**

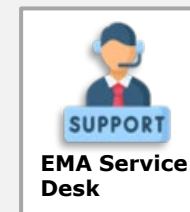
DMP EV Code is retrievable in CTIS **within 48 hours**



Sponsor

Correct data as per XEVPRM ACK and re-submit

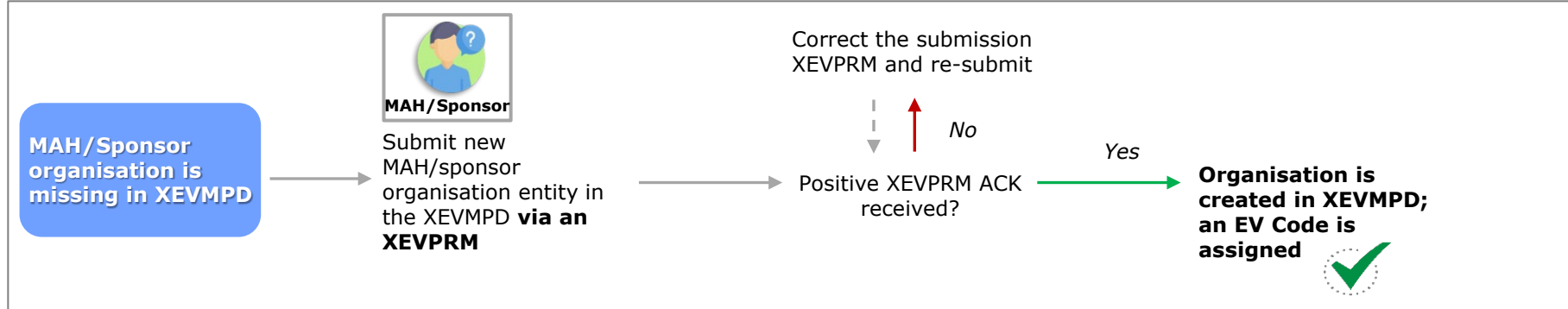
Questions & support



SUPPORT
EMA Service Desk

If a **MAH or sponsor organisation** information is missing in the XEVMPD

- Check if your organisation is in OMS; if not, request the addition of the organisation in OMS **via an [OMS change request in EMA Service Desk](#)**
- Insert it **via an XEVPRM as it is entered in OMS** and **reference the Loc ID in the 'Comment' field of the organisation**

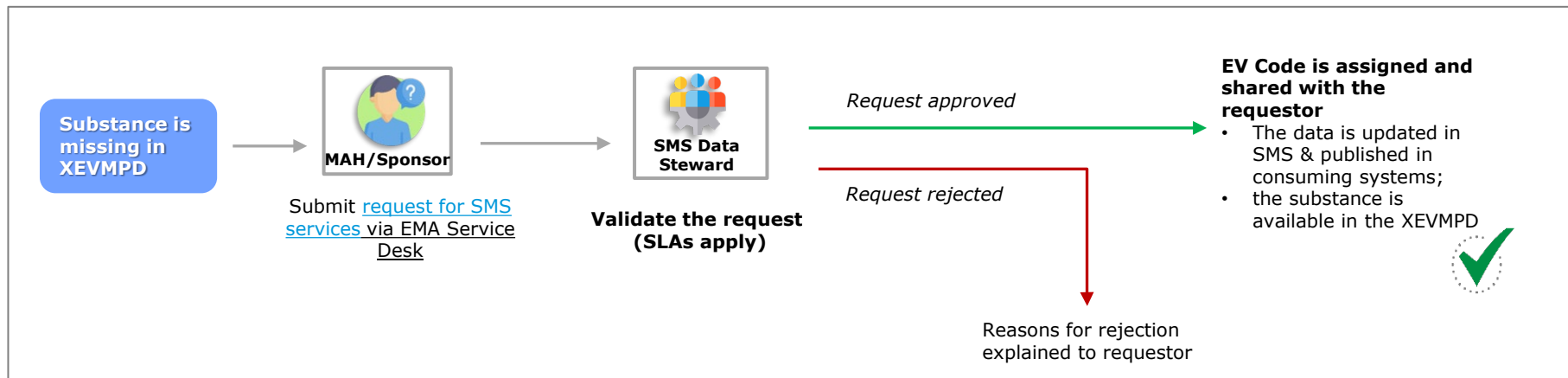


List of MAH and sponsor organisations available in the XEVMPD:

- XEVMPD 'Sponsors' or 'MAH' look-up tables
- OMS extracts in the [OMS portal](#) (*The EV code of an organisation can be found in the 'Mappings' section of the organisation in OMS*)

If a **substance** information is missing in the XEVMPD and it is not/cannot be **re-mapped to another existing approved substance**

- Request the addition of the substance information in the XEVMPD via EMA Service Desk [request for SMS services](#)

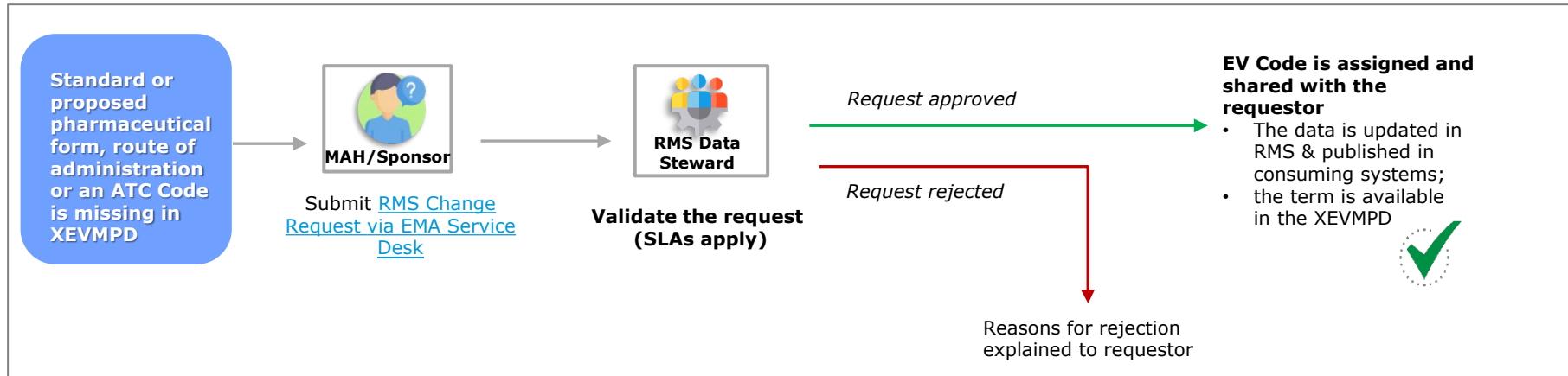


List of substances available in the XEVMPD:

- XEVMPD look-up tables ('Approved Substances' or 'Development substances')
- SMS substance extracts in the [SMS portal](#)

If **pharmaceutical form**, **route of administration** or **an ATC Code** is missing in the XEVMPD and the terms are not/cannot be **re-mapped to another existing term**

- request the addition of the term in the XEVMPD via an [RMS change request in EMA Service Desk](#)

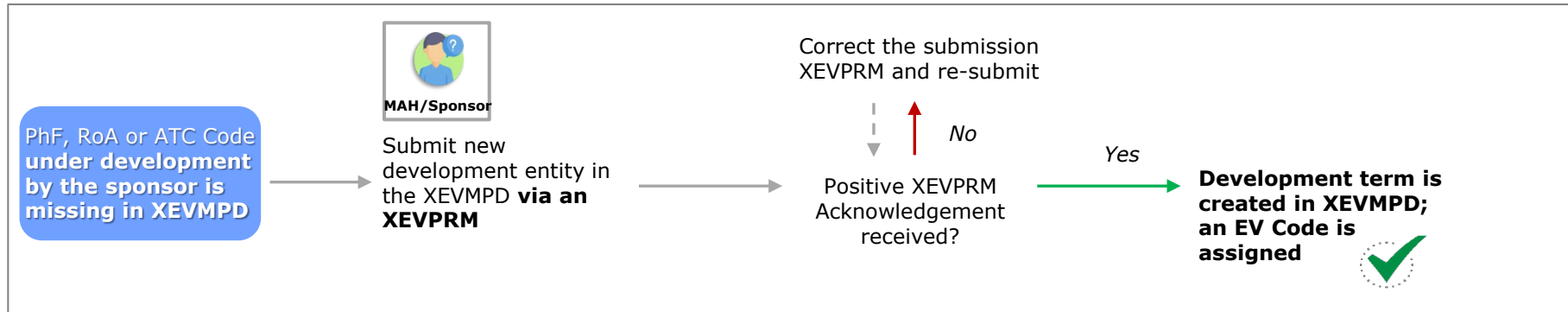


Lists of PFs/RoA/ATC Codes available in the XEVMPD can be retrieved from:

- XEVMPD 'Pharmaceutical Forms', 'Routes of Administration', ATC Codes look-up tables
- RMS lists in the [RMS portal](#)
- List of proposed terms that can be mapped to standard terms is available in the 'Documents' section of the [RMS portal](#)

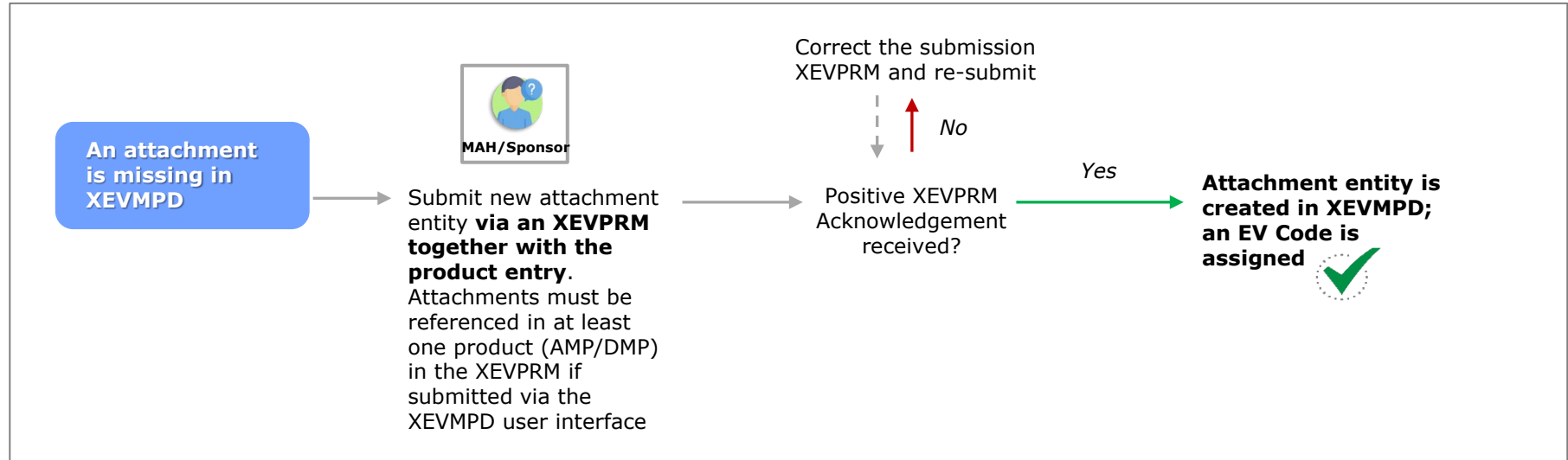
MAH/sponsors can also submit in the XEVMPD '**development terms**' for a pharmaceutical form, route of administration and an ATC Code:

- **terms that are still under development** and the **information about such terms is considered confidential**;
- **can only be referenced in development product entries**;
- sponsor-specific; only the owner organisation can reference such terms in their DMPs;
- **must not match any current standard or proposed term already present in the XEVMPD.**



If the required **attachment** entity is missing in the XEVMPD

- submit the attachment entity in the XEVMPD via an XEVPRM



- Optional to reference attachments in DMPs
- Can be retrieved from XEVMPD 'Attachments' look-up table