



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) e-learning

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Registration with EudraVigilance

Version 5.7





To submit medicinal product information in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD):

- Organisations (e.g. applicants, MAH, sponsors) must be registered in the [Organisations Management System \(OMS\)](#).
- The MAH/sponsor organisation must also [register with EudraVigilance](#) for **medicinal product reporting**
  - Clinical research organisations (CROs), IT vendors and third-party service providers must be registered in EV under MAH/sponsor organisation profiles
    - Independent registration with their own EudraVigilance ID is not possible
    - They can only submit information on behalf of MAH/sponsors registered in EV, using the MAH's/sponsor's organisation ID



- Each MAH/sponsor organisation must have a EudraVigilance **headquarter (HQ) profile** created
- Additional organisation profiles ('**affiliate**' and/or '**virtual affiliate**') can be created under the main HQ profile

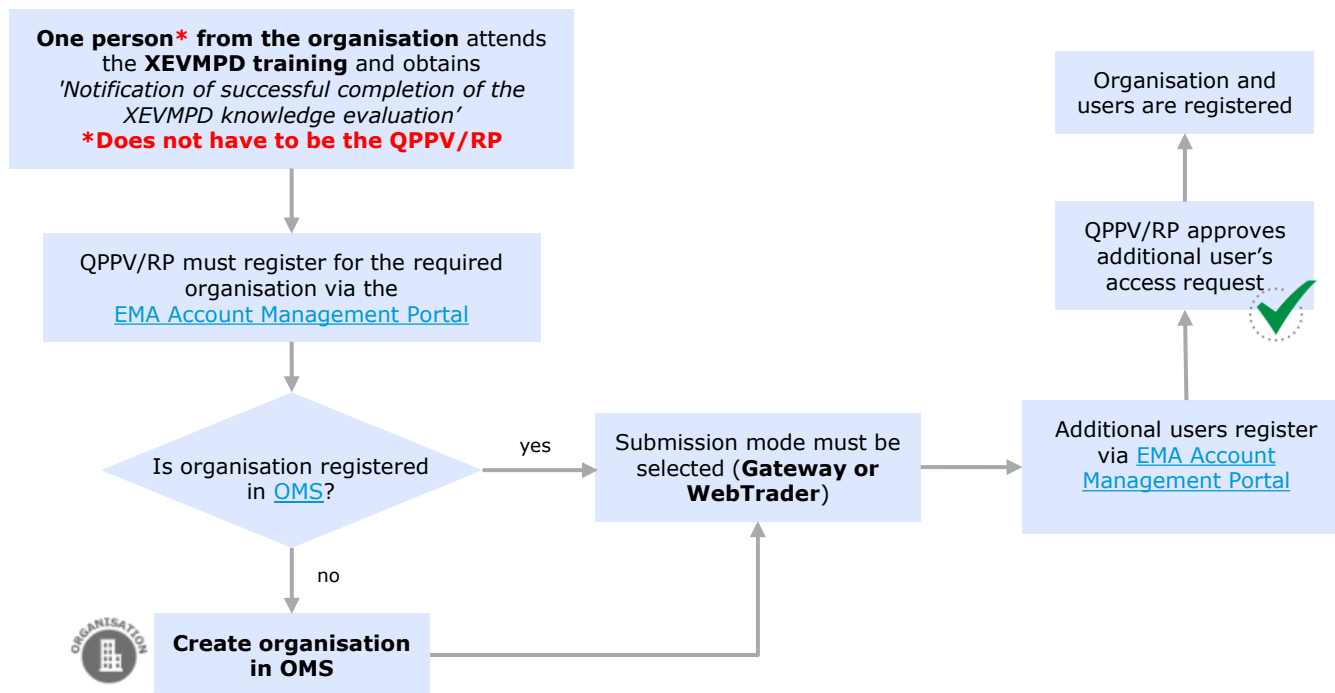




- Individual users must request access **for the required organisation** via the [EMA Account Management Platform \(IAM\)](#):
  - Each **MAH organisation** must have an EU Qualified Person Responsible for pharmacovigilance (QPPV) associated with their headquarter (HQ) profile
  - Each **sponsor organisation** must have a Responsible person (RP) associated with their headquarter (HQ) profile
- EU QPPV/RP and/or their Trusted Deputy (TD) approve access for other users from their organisation.



All available user roles are described in *Annex 1 - EV "base" and "supplementary" roles* of the [EMA EudraVigilance Registration Manual](#)





- ['EudraVigilance: How to register' webpage](#)
- [EudraVigilance registration manual](#)
- EudraVigilance Registration queries should be submitted via the [relevant form in the EMA Service Desk Portal](#)