21 May 2014
EMA/220372/2014
European Medicines Agency

# Call for expression of interest

## Access to eXtended Medicinal Product Dictionary (XEVMPD) test environment (XCOMP) for software vendors

The purpose of this call is to collect interest of third parties wishing to test the electronic transmission of eXtended Medicinal Product Report Messages (XEVPRMs) with the European Medicines Agency (EMA), including software providers (or independent software vendors, hereinafter referred to as "ISV") in order to make appropriate testing arrangements.

### *Background*

As of 16 June 2014 and by 31 December 2014 at the latest, marketing authorisation holders (MAHs) are required to update, complete and improve the quality of medicinal product data submitted in the context of Art 57(2) of Regulation (EC) No 726/2004, and submit to the EMA information on all medicinal products submitted under Article 57(2) provisions, and in compliance with the new XEVPRM format published by the Agency on 31 January 2014. Marketing authorisation holders can submit such information in the XEVMPD via the WEB Trader component of XEVMPD Data Entry Tool (also known as EVWEB) or using dedicated software that may be provided by Third Party Service providers or ISV.

When the EMA changes the structure, content or specifications of the XEVPRM format, third parties using the software products have to make changes to their own software specifications, in order to be compliant with the latest messaging specifications defined by the EMA. Failure to make these changes by the required deadline might impair the correct and efficient flow of technical information between the EMA and MAHs; for example, the electronic messages sent with a non-compliant version of the software could be rejected by the XEVMPD system.

In order to allow third parties, and in particular ISV organisations, to develop updated version of their software platforms in a short time frame, and following a specific request from the Article 57 Implementation Working Group (IWG), the EMA intends to provide interested parties with the possibility to test their own software systems in a controlled environment.

The EMA will allow independent software vendors to test (between June and December 2014) the capability of their software, to produce XEVPRMs compliant with the latest regulatory specifications by means of connecting to the EMA test environment gateway to submit XEVPRMs and receive Acknowledgement messages from the XEVMPD test database.

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### *How to apply*

Organisations intending to apply for a test trial will be registered in advance, and will be given the possibility to exchange XEVPRMs and receive Acknowledgement Messages by means of the EudraVigilance Gateway. In order to use the EudraVigilance Gateway for secure XEVPRM message exchange, interested parties must provide the EMA with the necessary information in order for the EMA to create an organisation profile.

Interested parties are asked to submit an email request to the dedicated email address VendorTesting@ema.europa.eu. The following information must be provided:

- Name of organisation;
- Address details or organisation;
- Name of contact person;
- Telephone, fax number and email address of contact person.

Applicants will be registered on a “first come first serve” basis and will be duly notified of their successful registration.

### *Next steps*

Maximum of 20 software vendors per calendar month can be registered. The registration will occur on a rolling basis.

Following the registration of successful applicants, the registered organisation will be contacted and provided with the necessary forms/documents to be submitted to the EudraVigilance Registration team. Once the organisation profile is created in the EudraVigilance database, and the Gateway set up has been completed, the software vendor will be contacted to commence the testing. When a successful connection has been established, medicinal product report and acknowledgement messages can be successfully transferred between each party and uploaded in the XEVMPD.

### *Disclaimers*

- The EMA will specify a time-based and conditional access. In the event of technical/security issue, the EMA will have the right to close the service down – either temporarily or permanently.
- No service level agreement(s) will be offered by the EMA.
- No access to the data held in the XEVMPD database and therefore to the EVWEB interface will be provided – no login details to EVWEB will be provided to the ISV organisation.
- Interested organisations are reminded that the use of the testing facility does not represent and should not be construed to represent an official endorsement/certification by EMA of any commercial services.
- To avoid any further registration system adjustments and to reduce the complexity of the registration process, organisations will be registered with a “marketing authorisation” profile. The organisation ID of each software vendor will be assigned by the EMA and will consist of the text "ISV" followed by a numerical sequence (e.g. ISV01, ISV02 etc.).