



Information for pharmaceutical companies

Electronic exchanges of individual case safety reports (ICSRs) with Afssaps

Version 1.0 – September 29, 2006

Overview

This document addresses the exchange of individual case safety reports (ICSRs) on adverse reactions to medicinal products occurring post-marketing. The exchange of cases of suspected unexpected serious adverse reactions (SUSARs) occurring in clinical trial settings will be addressed in another document to be posted subsequently.

This posting, which provisionally addresses the technical phase of testing electronic exchange of ICSRs between companies and Afssaps, will be regularly expanded and updated.

The Afssaps Pharmacovigilance Unit has deployed a new system compliant with the international standards for the electronic exchange of case safety reports. The application supports transmission and reception of ICSRs in XML format in compliance with recommendations ICH E2B(M), M1 and M2(M) (DTD version 2.1). The MedDRA terms used are to be the current terms in the most recently published version of that terminology.

The overall process of the EudraVigilance electronic exchange community and the conditions for registering with the community are described in detail on the EudraVigilance website (<http://eudravigilance.emea.eu.int>).

The Afssaps application uses the routing functions of the EudraVigilance gateway (EV ESTR1 Gateway) (<http://eudravigilance.emea.eu.int/human/evGateway01.asp>) that supports two-way exchange of ICSRs between companies and competent authorities without the cases being loaded into the European database. The gateway also enables cases to be loaded into the European database.

The business rules for the Afssaps application are the same as those for the EudraVigilance system (Doc. Ref. EMEA/H/20665/04/Final).

In order to obtain the authorization to transmit and receive ICSRs in the production environment from Afssaps, companies are required to successfully complete a certification testing phase described below.

The languages accepted by Afssaps for ICSR transmission are French and English.

The conditions governing inclusion of causality assessments scored using the French method in the ICSRs will be posted shortly. The conditions will ensure compliance with the ICH recommendations cited above.

Prerequisites for the certification testing phase

Each company candidate for the certification testing phase is required to pre-register with the EMEA as a EudraVigilance community partner.

Each candidate is required to have successfully completed the transmission tests in the EudraVigilance test environment.

Certification testing phase

A company questionnaire will be posted on this site shortly.

The certification testing phase consists of four stages:

1. Transmission to Afssaps, by the candidate, of the above company questionnaire, which mainly addresses:
 - The contributors' names and contact details
 - Test and production identifiers (Interchange IDs)
 - The company's ability to electronically transmit and receive ICSRs
2. Contacting the company (initiated by Afssaps)
3. Testing the feasibility of ICSR transmission from the company to Afssaps
 - Transmission of a set of test files to Afssaps by the company
 - Verification of the test files by Afssaps
 - Certification of the company's ability to electronically transmit ICSRs by Afssaps
4. Testing the feasibility of ICSR transmission from Afssaps to the company
 - Transmission of a set of test files to the company by Afssaps
 - Verification of the test files by the company
 - Company's agreement to electronic transmission of ICSRs to the company by Afssaps

The content of the test files will be very similar to that required by the EMEA for certification of transmission in the EudraVigilance test environment.

Certification testing phase schedule

Due to events outside of Afssaps' control, the certification testing phase has fallen behind the schedule announced some months ago, but should begin in October 2006. As soon as a firm date has been determined it will be posted on this site.