

REPORTS OF SUSPECTED ADVERSE REACTIONS FROM THE LITERATURE: INFORMATION FOR THE PHARMACEUTICAL INDUSTRY

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The Spanish Agency of Medicines and Medical Devices (AEMPS) announces its decision to waive Marketing Authorization Holders (MAH) the reporting of cases from the literature that have already been reported to the Spanish Pharmacovigilance System (SEFV-H). The AEMPS will make available on its website a list of literature reports already registered in FEDRA (Spanish Pharmacovigilance System Database). The list will be updated daily.

Information for MAH:

Before submission of an expedited literature report to the AEMPS, the MAH should review the list of literature reports published on the website (www.aemps.gob.es).

1. If the literature report can be identified in the list, the report should not be expedited to the AEMPS.

MAH should ensure their internal procedures are updated to include the steps to follow in these cases by adding in the ICSR the following fields that appear in the list:

- “Worldwide number” (E2B field A.1.10)
 - “Date of publication on the website”
 - A record should be added indicating that the reference has been located in the AEMPS literature list with a date
2. If the literature report cannot be identified in the list, the ICSR should be expedited to the AEMPS according to current legislation. An email containing the original paper (as a PDF file attachment) will be sent to the following e-mail address fvicsr@aemps.es.
 3. When a case is identified through a secondary journal reference such as, Journal REACTIONS WEEKLY, the ICSR should be expedited. In these cases, and if the ICSR includes the minimum information for reporting, then the ICSR should be expedited with the primary literature reference included.

Where the MAH has already submitted an ICSR with only the secondary journal reference (eg. journal REACTION WEEKLY reference), then they should electronically submit a follow up case with the primary journal reference. Accordingly, an email should be sent with the PDF file of the original paper to the following e-mail address fvicsr@aemps.es.

Information for Contract Research Organizations (CROs) or service companies performing literature searches on behalf of MAH.

Contract Research Organizations (CROs) or service companies performing literature searches on behalf of MAH, should follow the same instructions given for MAH.

Additionally, when identifying a literature report with an active substance authorised for several MAH, for which they are working on their behalf:

- A single case (ICSR) must be submitted to AEMPS assigned to one of the MAH.
- The article should be emailed once with the PDF file attached and named with the ICSR worldwide Lumber.
- Submission of ICSRs for the other MAHs will be waived. A report in the ICSRs not being submitted, will be made indicating that the literature report has been identified in the AEMPS website literature list.