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EMA/141813/2015, Rev 4\*  
Data Analytics and Methods

# Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency

Description of the Journal/Reference databases used

\*Note: Revision 4 includes the following:

- Inclusion of the MEDLINE database;
- Removal of reference to EBSCO
- Updated links to IPA and AMED databases;
- Minor formatting amendments

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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## Background

Article 27 of Regulation (EC) No 726/2004 sets out the following:

1. The Agency shall monitor selected medical literature for reports of suspected adverse reactions to medicinal products containing certain active substances. It shall publish a list of active substances being monitored and the medical literature subject to this monitoring.
2. The Agency shall enter into the EudraVigilance database relevant information from the selected medical literature.
3. The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database.

The literature subject to the monitoring activities by the Agency as outlined above has been defined in accordance with the provisions set out in the [Guideline on good pharmacovigilance practices \(GVP\) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products](#) and is based on the use of literature reference databases.

A description of these literature reference databases including their journal coverage is provided below.

## Description of the Journal/Reference databases

- [EMBASE](#), a large, comprehensive and widely used, daily updated and indexed biomedical reference database covering literature from EEA and non-EEA countries. Its coverage includes licensed Medline records and >3,200 other journals.
  - Information regarding EMBASE coverage, including the EMBASE indexing guide, the latest list of covered conferences and the latest list of journal titles in Embase, can be accessed [here](#).
- [MEDLINE](#), the United States National Library of Medicine's (NLM) bibliographic database is an international bibliographic reference database that contains millions of references to journal articles in life sciences with a concentration on biomedicine. It is the primary component of PubMed, a literature database developed and maintained by the NLM National Center for Biotechnology Information (NCBI).
  - The list of journal titles in the MEDLINE database is available [here](#).
- [International Pharmaceutical Abstracts \(IPA\)](#) covering a broad spectrum of drug therapy and pharmaceutical information from over 800 pharmaceutical, medical, and health-related journals. The list of journal titles in the IPA database, as of November 2022<sup>1</sup>, is available [here](#).
- [The Allied and the Complementary Medicine Database \(AMED\)](#)<sup>2</sup> covering alternative treatments based on bibliographic records for relevant articles from 500 journals. The scope of coverage within this resource is mainly European.  
Information regarding AMED coverage can be accessed using the link above. Click the link in the sentence "Use the AMED Journals List (Excel) to help you find material on the Allied and Complimentary Medicine Database (AMED)."

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<sup>1</sup> This is the most recent version the Agency has obtained from the database providers at the time of publishing.

<sup>2</sup> As of the date of publication of revision 4, this link is broken because the British Library, which provides the AMED database, is continuing to experience a major technology outage as a result of a cyber-attack.