



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees

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

Background

Article 27 of Regulation (EC) No 726/2004¹ 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 Good Pharmacovigilance Practices (GVP) guideline, Module VI 'Management and reporting of 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.

*Note: Revision 2 includes the following:

- Links to the list of journal titles in EBSCO

¹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013).



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.
 - 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](#),
 - EMBASE coverage includes licensed Medline records and >2,700 other journals;
- [EBSCO](#) covers a wide variety of resources, whereby the main focus will be put on the use of:
 - [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 2016, is available [here](#);
 - [The Allied and the Complementary Medicine Database \(AMED\)](#) covering alternative treatments based on bibliographic records for relevant articles from nearly 600 journals. The scope of coverage within this resource is mainly European,
 - The list of journal titles in the AMED database, as of November 2016, is available [here](#).