EudraVigilance

Introduction

EudraVigilance is an EU web-based information system, designed to manage safety report data created by the European Medicines Agency (EMA) containing adverse reaction reports (ADRs) for medicines authorised in the EU. The ADRs are collected in a EudraVigilance database. While the Eudravigilance database is not publicly available, a website with the same data for the members of public exists: The European database of suspected adverse drug reaction reports.

The reporting of suspected ADRs in a consistent way across the European Economic Area (EEA) is very important. This helps to monitor the benefits and risks of medicines and to detect emerging safety signals. A safety signal can be defined as new information related to known ADRs or any other event, either adverse or beneficial, that is potentially causally related to the use of a medicinal product and that requires further investigation.

Safety signals are identified within EudraVigilance by performing a regular analysis of reports on such events.

Data collected in EudraVigilance database

ADR reports are received from the National Competent Authorities (NCAs), marketing authorisation holders (MAHs), sponsors of clinical trials, patients, and healthcare professionals. EudraVigilance is a repository of both EU and non-EU ADRs for ‘investigational’ and authorised medicines. EudraVigilance also incorporates the ‘Medical Dictionary for Regulatory Activities’ (MedDRA), which contains international

medical terminology.

There are two modules for the collection of data within EudraVigilance database.

The **pre-authorisation** module collects:

- Suspected unexpected serious adverse reactions (SUSARs) reported by sponsors of clinical trials
- Data from interventional clinical trials

The **post-authorisation** module collects:

- Suspected serious adverse reactions
- Healthcare professionals' spontaneous reporting
- Post-authorisation studies (non-interventional)
- Worldwide scientific literature (spontaneous, non-interventional)
- Transmission of an infectious agent via a medicine

The EMA has been operating a signal-detection process for centrally authorised medicines since July 2012. It also supports the EU Member States in their signal-detection processes for nationally authorised medicines. The EudraVigilance database is the main source of signals that may trigger regulatory action.

Reports of suspected adverse drug reactions (ADRs)

The European database of suspected adverse drug reaction reports is available online at http://www.adrreports.eu. It already contains millions of suspected ADRs. The database is available to sponsors and research organisations, marketing authorisation holders (MAHs) in the EEA, healthcare professionals, and the general public.

Adverse reaction data is grouped and users can search by defined parameters (for instance product (medicines), active

substance, reaction, age group, gender, time period). There are ‘Download’ and ‘Print’ functions for search results. This might be a summary or individual reports based on defined data elements ensuring compliance with personal data protection legislation. Users are provided with clear guidance on the interpretation of data. Of the approximately 220 data elements per report, access will be granted to around 25%.

Interpreting the data on European databases

The information on the databases relate to suspected adverse reactions – for instance, the effects that have been observed following the administration of, or treatment with, a medicine. However, these suspected adverse reactions **may not be related to, or caused by, the medicine.**

Be advised that the information on this website **cannot be used to determine the likelihood of experiencing an adverse reaction**.

Other information, such as how many people take the medicine and how long it has been on the market, must be considered when interpreting the data.

Further Resources

- The European database of suspected adverse drug reaction reports is available in 24 European languages from http://www.adrreports.eu/ (Retrieved 11 September, 2015).
- More information on EudraVigilance is available from https://eudravigilance.ema.europa.eu/highres.htm (Retrieved 11 September, 2015).

Attachments

- Presentation: EudraVigilance

  Size: 372,115 bytes, Format: .pptx

  A presentation describing the EudraVigilance information system, which can be adapted for own use.

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