EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Pharmacovigilance: Information systems and services

Supporting business activities of the revised pharmacovigilance legislation through better information systems

An agency of the European Union

To deliver the IT systems needed to support business activities of the revised pharmacovigilance legislation and to change the relevant business functions to maximise the benefits for stakeholders.

Medical Literature Monitoring

Scope: EMA to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances and to enter individual case safety reports into the EU adverse reaction database (EudraVigilance).

Benefits:

- This will improve safety monitoring of medicines through better quality of safety information (less duplicate reports);
- This will reduce the administrative burden on MAHs for the relevant substances (EMA service to MAHs).

Adverse Drug Reaction Reporting and Signal Management

Scope: There is a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, better quality data and better searching, analysis and tracking functionalities. Enhanced detection of new or changing safety issues allows more rapid action to protect public health. There is also a legal

requirement for MAHs to monitor data they have access to in EudraVigilance.

Benefits:

- Compliance with international data standards and future compatibility with ISO IDMP standards (based on Article 57 data) including backwards and forwards conversion tools for E2B(R2)/(R3) messages;
- Improved performance and scalability of new system to cope with foreseen increase in users and volume of data;
- Simplified reporting whereby MAHs no longer report to National authorities (reports access through EudraVigilance).

PSUR repository

Scope: Legal requirement for EMA to set up a repository for periodic safety update reports (PSURs) and their assessment reports. This will allow centralised PSUR reporting and to enhance access to data and information, thereby supporting benefit risk assessments of medicines.

Benefits:

- Provides a simplification of PSUR submissions benefiting pharmaceutical industry (PSURs submitted electronically to the Repository, submissions accessible to regulators);
- Once the use of the Repository is mandatory, it will include all PSURs, including those that follow the PSUR Single Assessment and those PSURs which are not part of a Single Assessment;

- Delivers a user interface to upload assessment reports and comments by the National Competent Authorities to the repository;
- Delivers a user interface to regulators to query and retrieve documents by use of metadata based on fields present in the list of EU reference dates.

Art57 database of medicinal products

Scope: To deliver structured and quality assured information on medicinal products authorised in the EU that can support EU terminologies of products, substances, and organisations used to power pharmacovigilance and regulatory systems in the EU.

Benefits:

- Facilitates the coordination of regulatory decisions and actions to safeguard public health, including identification of products and substances in reports of suspected adverse drug reactions;
- Strengthen transparency and communication with stakeholders by allowing to grant access to safety data, efficiently exchanging data within the EU Network and international partners, and supporting communication between the Agency's Committees and the pharmaceutical industry;
- Supports the reduction of duplication of encoding and maintenance of the same information on medicines, thus reducing costs (i.e. implement a single database and set of terminologies for multiple uses).

Enhanced Pharmacovigilance through effective implementation of information systems and services

New EU Pharmacovigilance legislation has been operational since July 2012. The legislation foresees various information systems to enhance pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. These systems will contribute to public health through optimisation of the safe and effective use of medicines. The suite of projects which are implementing these information systems are:

- Medical Literature Monitoring (MLM);
- Adverse Drug Reaction Reporting and Signal Management;
- PSUR repository;
- Article 57 database of medicinal products (Art57).

Resources on the Agency's website

Human Regulatory > Pharmacovigilance
Pharmacovigilance legislation > Implementation

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