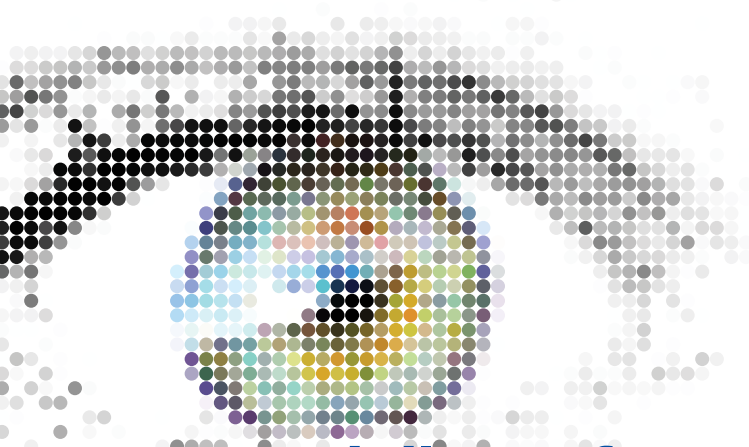
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Better vigilance for health protection and innovation

Overview of the new EU pharmacovigilance legislation

An agency of the European Union

More robust pharmacovigilance for better health protection

The new pharmacovigilance legislation[1], adopted in the European Union (EU) in December 2010 and amended in October 2012, aims to promote and protect public health and save potentially thousands of lives each year by:

- strengthening the European system for monitoring the safety and use of medicines;
- clarifying and simplifying tasks for the parties involved;
- improving decision-making procedures and reducing administrative costs;
- strengthening communication and transparency on the safety of medicines.

This legislation is the biggest change to the regulation of human medicines in the EU since 1995. It increases the vigilance of the system, allowing regulators to respond more rapidly and robustly, in the interest of protecting public health, when safety issues relating to the use of medicines arise.
It also supports innovation by ensure robust systems support products entering the market.

[1] Regulation (EU) No 1235/2010 and Directive 2010/84/EU

New pharmacovigilance legislation will improve the safety-monitoring of medicines in Europe, support innovation and save lives.

Why is this new legislation necessary?

No medicine is completely safe, and all can potentially have harmful side effects, known as adverse drug reactions (ADRs). Currently, some 197,000 people in the European Union (EU) die each year as a result of ADRs.

All medicines in the EU undergo strict safety testing before being authorised for use, and are continuously monitored thereafter so that ADRs can be detected, assessed and prevented.

This monitoring, called pharmacovigilance, is conducted in accordance with robust legislation that ensures the EU has one of the world's most advanced pharmacovigilance systems.

The system involves many responsible parties, including pharmaceutical companies, patients, healthcare professionals, national regulatory authorities, the European Medicines Agency (as coordinator of the system) and the European Commission.

Recognising that there were opportunities to further strengthen and rationalise the system, the EU passed new legislation in December 2010, further amended in October 2012 that greatly improves public-health protection and will save lives by enhancing the overall efficiency and effectiveness of the system.

Key benefits of the new legislation

The new pharmacovigilance legislation, which came into effect in July 2012, offers these major benefits:

- More clearly defined roles and responsibilities of the many actors involved.
- Simplified tasks, with less duplication of effort.
- Reduced costs and administrative burden.
- Strengthened reporting systems for collection of high-quality data on the safety of medicines.
- More rigorous, science-based approach that integrates the concepts of benefit-risk balance and risk management planning.
- Greater engagement of patients and healthcare professionals.
- More and better information provided to the public, with greater transparency of decision making processes.

It is estimated that these measures could save up to approximately 5,000 lives, while providing savings to society of some €2.5 billion per year in the EU.

Robust planning of post-authorisation data collection and systems are also critical to support innovation, as they provide the confidence that any safety issues will be detected and resolved rapidly, once a product enters the market.

Role of the European Medicines Agency

The European Medicines Agency, the EU Member States and the European Commission are responsible for implementing much of the pharmacovigilance legislation. The Agency plays a key role in coordinating activities relating to the authorisation and supervision of medicines, including safety monitoring, across this network.

Priorities for implementation of new pharmacovigilance legislation have been firstly public health activities, secondly transparency and communication activities and thirdly simplification activities. Based on this prioritised implementation, most of the new pharmacovigilance legislation provisions are now fully operational with ongoing implementation on the delivery of some new information systems.

Further details on implementation

Details of the specific legislative elements the Agency is implementing are covered in four 'blocks' of activities:

- Collection of key information on medicines;
- Better analysis and understanding of data and information;
- Regulatory action to safeguard public health;
- Communication with stakeholders.

Resources on the Agency's website

Human Regulatory > Pharmacovigilance
Pharmacovigilance legislation > Implementation

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