EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Pharmacovigilance

An agency of the European Union

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions and other medicine-related problems.

Benefit-risk balance

Medicines may affect the body in unintended, harmful ways. These effects, called side effects or adverse reactions, represent risks of medicines.

At the time when a new medicine obtains a marketing authorisation, the active substance has been tested and the data have allowed a conclusion to be drawn that the benefits of the medicine outweigh its risks.

However, once the medicine has obtained a marketing authorisation, it will be used in normal healthcare settings for many patients who may differ from the study population, for example by age or additional diseases.

It is therefore important to identify any new or changing risk of a medicine as quickly as possible, and to take measures to minimise risk and promote safe and effective use.

Pharmacovigilance by pharmaceutical companies

The company that holds the marketing authorisation for a medicine has legal obligations to continuously collect data and conduct pharmacovigilance.

Data have to be transmitted to the authorities within defined timelines, and any emerging concern about the benefit-risk balance has to be notified immediately.

If necessary, the authorities may request further investigations, including formal studies. Regulatory procedures exist for updating product information and implementing other safety measures.

The EU pharmacovigilance system

The regulatory pharmacovigilance system of the European Union comprises:

- the competent authorities for the regulation of medicines in the Member States;
- the European Commission as the competent authority for medicinal products authorised centrally in the EU;
- the European Medicines Agency, with responsibilities for centrally authorised products and system coordination.

Tasks within the system

The EU system engages in the following tasks:

- Collecting data from all available sources, mainly case reports on individual patients and results from epidemiological studies and trials;
- Analysing data and identifying signals of possible new or changing risks;
- Assessing risk-management plans, case reports, study reports, periodic safety update reports and benefit-risk reviews submitted by marketing-authorisation holders;

- Inspecting marketing-authorisation holders;
- Evaluating risks, in terms of frequency, seriousness and risk factors;
- Managing risks, often through further investigations as well as risk-minimisation measures.

Coordinative systems at the Agency

The Agency supports the competent authorities in Member States and coordinates the system in particular by means of:

- EudraVigilance, the EU reporting and data-warehouse system for case reports;
- the EU Rapid Alert and Incident Management Systems for timely and adequate responses to new safety data;
- the Pharmacovigilance Risk Assessment Committee (PRAC), which provides recommendations on all aspects of pharmacovigilance and risk management;
- ENCePP, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, for facilitating independent multi-centre studies;
- good pharmaceutical practices (GVP) and other standards;
- developing scientific networks to improve the evidence for decision-making and the public-health effectiveness of pharmacovigilance.

Pharmacovigilance at the European Medicines Agency

Legal requirements related to the European Medicines Agency (EMA) pharmacovigilance system for human medicines are laid down in Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) No 520/2012.

In order to comply with its legal obligations related to the promotion and protection of public health through the safety monitoring of authorised medicinal products and to detect and confirm any change to their risk-benefit balance, the Agency operates a quality assured pharmacovigilance system.

The detailed operational requirements of all EMA pharmacovigilance tasks that constitute the EMA pharmacovigilance system are set out in the Agency's policies and which are part of the EMA's integrated quality management system and can be found on the Agency's website.

The EMA has a coordinating role in the functioning of the EU pharmacovigilance system in collaboration with the Member States and the European Commission.

Further information

European Medicines Agency
Pharmacovigilance Department

30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Telephone +44 (0)20 3660 6000
Facsimile +44 (0)20 3660 5525

Send a question www.ema.europa.eu/contact
Website www.ema.europa.eu