Biological and Biosimilar Medicines
Fact Sheet 4: Pharmacovigilance

International Alliance of Patients' Organizations
A global voice for patients

This Fact Sheet provides information about the monitoring and tracking of medicines once they have been approved in general and specifically in relation to biological and biosimilar medicines. It also provides some key questions for patients' organizations to consider in relation to pharmacovigilance.

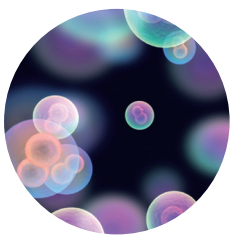
What is pharmacovigilance?

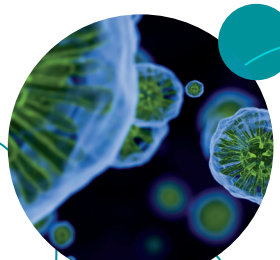
- Pharmacovigilance is defined by the World Health Organization (WHO) as:

  "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems."

Why is it important?

- Pharmacovigilance is a critical process for ensuring that all medicines, including biological medicines, are safe to use through monitoring adverse events in patients.
- Once any medicine is approved and available to patients, there is still a need to monitor the effects of the medicine.
- This procedure is known as **post-marketing surveillance** or **pharmacovigilance**.
- This is necessary because some **adverse drug reactions** (ADR) or effects may only become apparent when the medicine is used extensively in large numbers of patients.
- This may be because patients in clinical trials are selected and limited in number, the conditions of use will differ from those in clinical practice, and the duration of trials may be limited.
- An ADR is defined by WHO as: *"An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable."*
- All pharmaceutical companies are required to have pharmacovigilance systems in place for every drug that they manufacture.
- There are a number of systems in place around the world to monitor adverse drug reactions, both during clinical trials and once medicines have been put on the market. For example, in the European Union, suspected adverse drug reactions are reported through EudraVigilance, which collects and evaluates suspected adverse reactions.
- There is significant variation among the levels and types of pharmacovigilance systems in the regulatory authorities of different countries throughout the world.





Biological and biosimilar medicines

For biological medicines, pharmacovigilance is essential because:

- Biological medicines are very sensitive and changes in production methods or impurities can affect their likelihood of causing an immune response, making adverse drug reactions difficult to predict.
- Adverse effects may only arise after the patient has been taking the medicine for a long time.

All biological and biosimilar medicines must have a **pharmacovigilance plan** and a **plan to manage risk**.

- A plan to manage risk should include:
  - pharmacovigilance information on what is currently known about the safety of the medicine
  - how information will be gathered on safety once the medicine is available to patients
  - how risk will be managed if an adverse event occurs.
- Furthermore, as all biological medicines can change over time, e.g. due to manufacturing or environmental changes, manufacturers need to carefully monitor their medicines to effectively manage changes over time.

Key questions for patients' organizations to consider

In order to advocate for strong pharmacovigilance systems in your country, begin by thinking about the following questions:

- Who is in charge of monitoring adverse events in your country?
- What type of pharmacovigilance system is in place for tracking and monitoring adverse effects for all medicines, including biological and biosimilar medicines?
- How strong is the pharmacovigilance system in your country?
- Where can patients in your country report adverse drug reactions?
- Is there a regional pharmacovigilance system in your region, e.g. run by the World Health Organization?
- Can you work with other patients' organizations and doctors in your country to lobby for a strong and robust pharmacovigilance system?