

What is pharmacovigilance?

Patients will occasionally develop side effects to prescribed medicines which had not been discovered during clinical trials, these are known as adverse drug reactions. Medicine regulators across the EU have a series of processes in place to monitor and assess any unexpected reactions to a medicine. This process is called pharmacovigilance.

Patients, doctors, and pharmacists all need to be aware of the importance of reporting any reactions and the process of how this should be done. High quality pharmacovigilance processes are particularly important for biological medicines, as these are made up of large, complex molecules, with a raised likelihood that a patient may experience an adverse event.

Why is pharmacovigilance important for patients?

Pharmacovigilance and the reporting of adverse drug reactions are highly important to patients as it ensures that the medicines they are taking are safe. It helps medicines regulators to monitor and assess the efficacy and safety of individual medicines, ensuring that swift action can be taken to protect other patients if an adverse reaction is detected.

What is the new study on pharmacovigilance in the EU about?

Pharmacovigilance in the EU: Practical implementation across Member States, is a new piece of research carried out by Professor Michael Kaeding of the University of Duisburg Essen. The report examines how well EU pharmacovigilance legislation is being implemented by six member states: the UK, Germany, France, Finland, Poland, and Portugal. It focuses specifically on the reporting of adverse reactions to biologic medicines, and makes recommendations of how processes can be improved in each country to better protect patients.

What does Professor Kaeding's study find about the effectiveness of pharmacovigilance in Finland?

- ✓ Good level of awareness amongst health care professionals of the importance of reporting adverse reactions due to thorough education on pharmacovigilance.
- ✓ Monitoring agency Fimea has taken a lead in providing advanced training for health care professionals.

What does Professor Kaeding's study highlight as challenges for Finland?

- A lack of awareness around the ability of patients to report adverse events.
- A less effective reporting system for patients and nurses.
- Widespread underreporting of less serious adverse reactions.
- The complexity of the system around patient records.

What can I do to help improve the pharmacovigilance system in Finland?

Patients can suggest the following to policymakers to help improve the pharmacovigilance systems in Finland:

1. More awareness raising campaigns around the importance of the role of patients in reporting adverse reactions.
2. More emphasis on the importance of health care professionals reporting all reactions, not just the most serious.
3. Allowing nurses to submit electronic reports to help reduce the workload of doctors.

