

Pharmacovigilance in the UK – what you need to know

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 UK pharmacovigilance?

- ✓ The Yellow Card Scheme operated by the UK's monitoring body is well promoted and effective at recording adverse events.
- ✓ There is good collaboration between all bodies involved in the Yellow Card Scheme process.

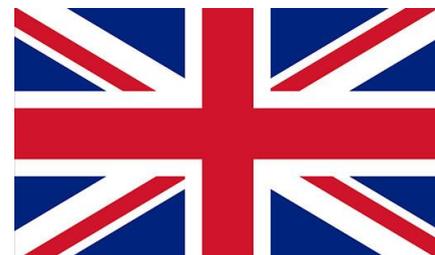
What does Professor Kaeding's study highlight as challenges for the UK?

- The complexity of the system for reporting adverse events.
- An ongoing lack of awareness about the Yellow Card Scheme among patients and healthcare professionals.
- A lack of academic programmes for trainee doctors on pharmacovigilance.

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

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

1. Further awareness raising campaigns around pharmacovigilance for patients and healthcare professionals.
2. Ensuring internal reporting processes are streamlined for simplicity.
3. Making academic training on the importance of pharmacovigilance mandatory for all for healthcare professionals.



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