

## Pharmacovigilance in Germany – 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 pharmacovigilance in Germany?

- ✓ There is a well-established pharmacovigilance system, with processes in place for sharing new information with doctors.
- ✓ There is good cooperation between the different agencies with responsibility for pharmacovigilance.

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

- A lack of awareness among patients and doctors regarding adverse event reporting, leading to resulting reports varying in quality.
- Gaps in the current academic education for doctors around pharmacovigilance.
- Pressure on the budgets available for pharmacovigilance systems.

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

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

1. Awareness raising campaigns to improve the understanding of pharmacovigilance among patients and health care professionals.
2. Ensuring a wide range of user friendly channels through which patients can report any adverse reactions.
3. Making academic training on the importance of pharmacovigilance mandatory for all for healthcare professionals.
4. Ensuring sufficient funding for monitoring agencies.

