Pharmacovigilance in France – 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 France?

- ✓ A decentralised pharmacovigilance system which makes it easy for healthcare professionals and patients to interact with.
- ✓ There are strong academic education programmes around pharmacovigilance for healthcare professionals.

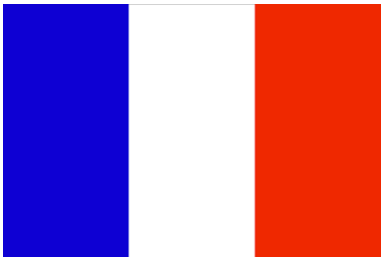
What does Professor Kaeding's study highlight as challenges for France?

- Underreporting of adverse events often due to healthcare professionals lacking time or resources, exaggerated by the complexity of the system.
- Reports which frequently include inaccuracies around medicine brand names.
- Concerns among healthcare professionals around possible litigation around decisions.
- Pressure on the budgets available for pharmacovigilance systems.

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

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

1. More awareness raising campaigns around pharmacovigilance for patients and healthcare professionals.
2. Additional training for doctors on the importance of reporting any adverse reactions particularly around biological medicines, including brand and batch number.
3. Streamline internal processes for reporting adverse drug reactions to improve cooperation between different agencies.



ansm
Agence nationale de sécurité du médicament et des produits de santé

For more information on pharmacovigilance, Professor Kaeding's study and patient advocacy, please do not hesitate to contact GAfPA on info@gafpa.org or via our website http://gafpa.org/