

# Pharmacovigilance: Advice for pharmacists

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Pharmacovigilance (PV) is identified by the World Health Organization as science and activities related to the identification, evaluation, understanding and prevention of adverse effects or any other drug-related issue. By providing a mechanism to collect, review, and distribute drug safety data, the aims of PV are to improve patient safety with regard to medication use. PV tasks include the tracking of licensed drugs and investigational medicines (IMPs) in order to :

- Identify previously unknown adverse effects.
- Identify improvements in the incidence or severity of reported adverse effects.
- Assess the risk/benefit of drugs to decide whether action is needed to improve safety.
- Ensure that information transmitted to healthcare practitioners and patients is correct and that information in patient information leaflets (PILs) is up-to-date.

## Need

In order for a medicinal product to be approved for use in the UK by a regulatory authority, the advantages and risks of a medicinal product are carefully considered. Because it is impossible to know exactly all information about a drug until it is approved, a balance must be found between making a new medicine accessible to patients and providing sufficient information on the quality, safety and security of a product.

When a drug is introduced, continuous safety monitoring is important, since by the time the marketing authorisation is given the medicine would have been tested in a very small number of patients for a limited period of time.

## Importance

Pharmacovigilance is essential to the protection of drugs. The PV study carried out in Phase I, Phase II, and Phase III clinical trials provides data on the safety profile of the medication to drug makers. This data can, if appropriate, be used for further R&D or may be submitted to regulatory authorities to allow access to new markets.

Multiple organizations oversee international collaboration for pharmacovigilance. The World Health Organization (WHO) is one of the primary groups that facilitate the sharing of data between countries around the world..

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