

Pharmacovigilance: Understanding and preventing adverse effects from medicines



What is pharmacovigilance?

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. (1)

Why is pharmacovigilance needed?

It is estimated that adverse drug reactions (ADRs) are between the 4th and 6th largest cause of mortality in some countries. (2) Ten to 20% of hospital admissions are due to such reactions. (3-5) As well as threatening the health of patients and consumers of medicines, adverse drug reactions also place a heavy financial burden on health care services. Some countries spend up to 15-20% of their healthcare budget on drug-related problems. (6) Pharmacovigilance systems are in place to detect and prevent adverse drug reactions, protect public health, and reduce avoidable costs to the health care system.

What is the role of pharmacovigilance?

Pharmacovigilance plays an essential role in the early detection of the risks of drugs. Every medicine is tested on a relatively small proportion of the population before it is approved for use by the wider population, where previously undetected reactions can emerge. Each patient is a unique medicines user with a distinctive lifestyle and circumstances, meaning that each person can have a different reaction to the same medicine. Medicines causing serious ADRs need to be re-evaluated or removed from the market to protect public health.

In this way, pharmacovigilance can prevent adverse drug reactions (ADRs) and aid health professionals and consumers of medicines in making the best benefit/harm assessment for safe and effective pharmacotherapy.

Why is pharmacovigilance needed at the European and National levels?

A European pharmacovigilance centre can draw on the data-rich national agencies to piece together information on ADRs from European countries.

However, there are differences among countries (and even regions within countries) in the occurrence of ADRs and other drug-related problems. This may be due to differences in diseases and prescribing practices; genetics, diet and social context; drug manufacturing processes; drug distribution and use; as well as the use of traditional and complementary drugs (e.g. herbal remedies).

Data derived from within the country or region may have greater relevance and educational value and may encourage national regulatory decision-making. Information obtained in one country (e.g. the country of origin of the drug) may not be relevant to other parts of the world, where circumstances may differ.

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How is the pharmacovigilance system set-up?

Pharmacovigilance systems are usually established at the national level. The following bodies play a role in all Pharmacovigilance systems:

Drug regulatory agencies

Drug regulatory authorities (DRA) are responsible for assessing applications for a medicine's marketing approval and monitoring the safety of the medicine once it is on the market. The DRA is responsible for the approval of product information and updates based on new alerts or information. A reporting system is also established where health personnel can directly or indirectly (via a pharmaceutical company) spontaneously report an ADR.

Manufacturers / producers

Manufactures and producers are responsible for the safety of their medicines. The manufacturers do this by receiving reports from the DRAs, which are compiled in periodic safety reports (PSURs) and used as information to DRAs and for updating Summary of Product Characteristics. They are also responsible for monitoring ADRs in clinical trials. Finally, manufacturers create five year risk management plans that are required in the marketing approval process for some new medicines.

Health care professionals

Countries may determine the extent to which health personnel are obliged to report ADRs. Deaths, life threatening reactions and ADRs causing lasting damage must be reported. Some Member States also have mandatory reporting of ADRs causing hospitalization or prolonging hospital stay as well as new unknown ADRs.

Pharmacovigilance units

Some DRAs may have a pharmacovigilance unit while other countries have external units, either funded by government/DRA or other means. A few countries have a system of regional centres acting on behalf of the DRA. Most DRAs have safety boards, which are only advisory.

References

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