Postgraduate Certificate in Pharmacovigilance

Medical Writing in Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem (WHO, 2021). Medical writing in pharmacovigilance plays a crucial role in communicating critical safety information about medicines to healthcare professionals, regulatory authorities, and patients. This explanation will cover key terms and vocabulary related to medical writing in pharmacovigilance in the context of the Postgraduate Certificate in Pharmacovigilance.

1. Adverse Drug Reaction (ADR)
An adverse drug reaction (ADR) is a harmful and unintended response to a medicinal product (EMA, 2021a). ADRs can be classified as type A (augmented) or type B (bizarre) reactions. Type A reactions are predictable, dose-dependent, and related to the pharmacological properties of a drug. In contrast, type B reactions are unpredictable, not dose-dependent, and not related to the drug's pharmacological properties.

Example: A patient experiencing nausea after taking a high dose of an anti-inflammatory drug is an example of a type A ADR.

1. Signal Detection
Signal detection is the process of identifying new or changing safety information that may indicate a risk associated with a medicinal product (EMA, 2021b). Signal detection involves systematically reviewing and analyzing data from various sources, such as spontaneous reports, clinical trials, and literature.

Example: An increase in the number of reports of hepatotoxicity associated with a new drug may indicate a safety signal requiring further investigation.

1. Periodic Safety Update Report (PSUR)
A Periodic Safety Update Report (PSUR) is a periodic report that provides an updated assessment of the benefit-risk profile of a medicinal product (EMA, 2021c). PSURs are submitted to regulatory authorities at regular intervals, typically every six months for the first two years after marketing authorization and annually thereafter.

Example: A PSUR for a newly authorized medicine would include information on all suspected ADRs reported since the last PSUR, updated benefit-risk assessments, and any new safety concerns.

1. Risk Management Plan (RMP)
A Risk Management Plan (RMP) is a document that outlines a comprehensive plan for managing risks associated with a medicinal product (EMA, 2021d). The RMP includes information on the safety profile of the medicine, pharmacovigilance activities, risk minimization measures, and an evaluation plan.

Example: An RMP for a medicine with a known risk of QT prolongation would include information on the pharmacovigilance plan for monitoring this risk, recommendations for ECG monitoring, and a plan for evaluating the effectiveness of the risk minimization measures.

1. Drug Utilization Study (DUS)
A Drug Utilization Study (DUS) is an observational study that assesses the utilization and outcomes of medicinal products in routine clinical practice (WHO, 2021). DUSs can provide valuable information on the safety and effectiveness of medicines in real-world settings.

Example: A DUS of a new anti-diabetic drug could assess the prescribing patterns and clinical outcomes in patients with different levels of diabetes control.

1. Case Series
A case series is a collection of reports on a group of patients who have experienced similar adverse events after using a medicinal product (CDC, 2021). Case series can provide valuable information on the characteristics and outcomes of ADRs, particularly for rare or serious events.

Example: A case series of patients who experienced serious skin reactions after taking a new medication could help identify risk factors and potential mechanisms for this ADR.

1. Direct Healthcare Professional Communication (DHPC)
A Direct Healthcare Professional Communication (DHPC) is a letter or other communication directed to healthcare professionals that provides important safety information about a medicinal product (EMA, 2021e). DHPCs are used when there is a need to inform healthcare professionals of new safety information that may affect the prescribing or use of a medicine.

Example: A DHPC for a medicine with a new safety warning about an increased risk of liver injury would include information on the risk, recommendations for monitoring, and advice for managing the risk.

1. European Medicines Agency (EMA)
The European Medicines Agency (EMA) is a decentralized agency of the European Union responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU (EMA, 2021f). The EMA plays a critical role in ensuring the safety and efficacy of medicines in the EU and works closely with national regulatory authorities and pharmaceutical companies.

Example: The EMA is responsible for the scientific evaluation of new medicines before they can be authorized for marketing in the EU.

1. World Health Organization (WHO)
The World Health Organization (WHO) is a specialized agency of the United Nations responsible for international public health (WHO, 2021). The WHO plays a critical role in monitoring and responding to global health threats, including the safety of medicines.

Example: The WHO's Uppsala Monitoring Centre is the global hub for the WHO Program for International Drug Monitoring, which supports the collection, analysis, and communication of safety information on medicines.

1. International Council for Harmonisation (ICH)
The International Council for Harmonisation (ICH) is an international organization that brings together regulatory authorities and pharmaceutical industry representatives from the EU, Japan, and the US to harmonize regulatory requirements for medicines (ICH, 2021). The ICH develops guidelines on topics such as safety, efficacy, and quality, with the aim of reducing differences in regulatory requirements and promoting the global development and availability of safe and effective medicines.

Example: The ICH E2D guideline on post-authorization safety studies provides guidance on the design, conduct, and reporting of safety studies after a medicine has been authorized for marketing.

In conclusion, medical writing in pharmacovigilance involves the use of specific terminology and concepts to communicate critical safety information about medicines. This explanation has covered key terms and vocabulary related to medical writing in pharmacovigilance, including ADRs, signal detection, PSURs, RMPs, DUSs, case series, DHPCs, EMA, WHO, and ICH. Understanding these terms and concepts is essential for effective communication in pharmacovigilance and for ensuring the safe and effective use of medicines.