



Pharmacovigilance Systems and Practices Across Europe

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DESCRIPTION

Pharmacovigilance in Europe represents a highly coordinated system designed to monitor the safety of medicines throughout their lifecycle. It involves a network of regulatory authorities, healthcare professionals, and pharmaceutical companies working together to detect, assess, and prevent adverse effects associated with medicinal products. This system ensures that medicines available to the public continue to meet acceptable safety standards even after they have been approved for use.

At the center of European pharmacovigilance is the European Medicines Agency, which plays a leading role in coordinating safety activities across member states. The agency collaborates with national regulatory authorities to oversee the collection and evaluation of safety data. One of its key responsibilities is maintaining a centralized database known as EudraVigilance, where reports of suspected adverse reactions are stored and analyzed. This database allows for the detection of safety signals that may not be visible within individual countries.

The European pharmacovigilance framework is supported by a strong legal foundation. Regulations and directives establish clear responsibilities for marketing authorization holders, requiring them to continuously monitor the safety of their products and report any concerns. These companies must submit periodic safety update reports that provide a comprehensive evaluation of the benefit-risk balance of their medicines. Regulatory authorities review these reports to determine whether any action is necessary, such as updating product information or implementing risk minimization measures.

Healthcare professionals and patients also play an essential role in the system. Spontaneous reporting of adverse drug reactions is encouraged across Europe, allowing real-world data to contribute to safety monitoring. Many countries have established national reporting systems that feed into the central database. Patients are increasingly recognized as valuable contributors, as they can provide firsthand accounts of their experiences with

medications. This inclusive approach enhances the quality and diversity of safety data.

Signal detection is a key activity within European pharmacovigilance. It involves identifying patterns or trends in reported data that may indicate a new or previously unrecognized risk. Advanced analytical methods are used to evaluate large volumes of data and highlight potential concerns. Once a signal is identified, it undergoes further assessment to determine its significance and whether regulatory action is required. This process ensures that potential risks are addressed in a timely manner.

Risk management is another important component. For each medicinal product, a risk management plan is developed to outline known and potential risks, along with strategies to minimize them. These strategies may include educational materials for healthcare providers, restrictions on use, or additional monitoring requirements. Risk management plans are continuously updated as new information becomes available, ensuring that safety measures remain relevant.

The Pharmacovigilance Risk Assessment Committee (PRAC), a specialized committee within the European system, is responsible for evaluating safety issues and making recommendations. It reviews data from various sources, including clinical trials, observational studies, and spontaneous reports. Its recommendations are then considered by other regulatory bodies before final decisions are made. This multi-level review process supports balanced and evidence-based outcomes.

Collaboration among European countries is a defining feature of the system. By sharing data and expertise, member states can respond more effectively to safety concerns. This collaborative approach also reduces duplication of efforts and ensures consistency in regulatory decisions. Harmonized guidelines, developed through international cooperation, further support alignment across the region.

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CONCLUSION

Pharmacovigilance in Europe is a well-structured and collaborative system that integrates regulatory oversight, scientific evaluation, and public participation. Ethical considerations are integral to pharmacovigilance practices. Protecting patient confidentiality and ensuring the responsible use of data are fundamental principles. Transparency in

communication is also important, as it helps maintain public trust in the safety of medicines. Regulatory authorities regularly publish safety updates and decisions, allowing stakeholders to stay informed. Through continuous monitoring, data sharing, and coordinated action, it ensures that the safety of medicines is maintained throughout their use. This approach not only protects public health but also supports the ongoing improvement of therapeutic practices across the region.