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Perspective

Pharmacovigilance Risk Management System and its Components

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DESCRIPTION

The World Health Organization (WHO) defines pharmacovigilance as science and activity related to the detection, assessment, understanding and prevention of drug side effects and other drug-related problems. The definition and scope of pharmacovigilance has evolved to recognize the importance of systemic approaches to monitoring and improving the safe use of medicines. In a simpler definition, pharmacovigilance is described as the process and science of monitoring drug safety and taking action to mitigate risk and increase profits. Therefore, the benefit risk assessment should start with a preclinical assessment of the drug and span its entire life cycle. As a result, after regulatory approval, safety and risk assessments have become increasingly focused when they are put on the market and prescribed to large numbers of people. There are no international standards governing the components of an appropriate pharmacovigilance system or the processes used in risk management, but there is an agreement among key regulators that pharmacovigilance is necessary and important in the development and marketing of medicines. Therefore, understanding the components, functions and processes required for complete and effective pharmacovigilance and risk management is essential when building clinical trial capabilities.

Risk management pharmacovigilance is composed of the following three components of individual medicines. 1) Safety Specifications: Significant side effects and significant missing information under investigation or suspected to be related to the drug. 2) Pharmacovigilance activities: Information gathering activities conducted in post-marketing surveillance. 3) Risk minimization activities: Safety measures activities to minimize risks, such as providing information to healthcare professionals and determining terms of use.

There are two types of activities for pharmacovigilance and risk minimization: "daily" and "additional" activities. Routine activities are activities carried out by a Marketing Approval Holder (MAH) for all drugs, such as collecting information on side effects of drugs and providing information through package inserts of drugs. Additional activities include "warning of new drugs in the early stages after marketing", "survey of user results", "post-marketing clinical trials" and "ensuring the proper use of drugs that require attention".

If PMDA determines the need for additional activities, such as during the approval process, PMDA will publish the RMP on PMDA's website after marketing approval holder submits an RMP containing the content of the additional activities to PMDA.

Risk management is a systematic approach to identifying, assessing, and understanding, acting and communicating risk issues. All medications carry risks, including side effects, drug interactions and the risk that the product may not function as expected. Manufacturers, regulatory agencies, medical professionals and patients all carry out risk management activities.

Drug safety a proactive approach to risk management is important throughout the drug life cycle. Our pharmacovigilance planning and risk management course critically reviews existing and evolving strategies to plan and optimize risk management activities for known and potential risks in newly approved products.

The risk management pharmacovigilance must be submitted as part of all new drug application documents, including generic and national applications and will be evaluated by the regulatory agency before the drug is approved. If we are concerned about risks that affects the balance between risk and benefit, regulatory agencies can also request RMP for approved products which do not having risk management pharmacovigilance.

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