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Risk Management in Pharmacovigilance

[1]Diksha Jitendra Medhane,[2]Dr. Sushil Patil
[1]UG Student, Mahavir Institute of Pharmacy, Nashik, Maharashtra,India.
[2]Professor, Mahavir Institute of Pharmacy, Nashik, Maharashtra,India.

Abstract –

Global adoption of risk management principles outlined in the
International Conference on Harmonisation (ICH) consistency into the practice of pharmacovigilance and benefit–risk management throughout the lifecycle of a drug. However, following the release of these guidelines there have been important advances in the science and practice of risk minimisation itself, especially in terms of how risk minimisation measures (RMMs) are designed, implemented, disseminated and evaluated for effectiveness in real-world healthcare settings.

Key words – Risk managrment, Pharmacovigilance, healthcare.

Introduction –

Proactive life-cycle risk management is a hallmark of modern pharmacovigilance and is based on complementary initiatives described by the Council for International Organizations of Medical Sciences (CIOMS) in its Working Group VI entitled "Management of Safety Information from Clinical Trials" and by the International Conference on Harmonisation (ICH) in the guideline entitled "Pharmacovigilance Planning" of 2004. ICH E2E outlined a structured, iterative process for identifying and assessing risks by introducing two foundational concepts: the Safety Specification that describes the product's risk profile, and the Pharmacovigilance Plan that describes how these risks are monitored and characterised.
Pharmacovigilance supports safe and appropriate use of drugs. Spontaneous reporting of adverse drug reactions (ADRs) is an essential component of pharmacovigilance.
Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem .

Need of study –

The need for global harmonisation that reduces duplication of currently disparate approaches (such as reporting formats), results in more effective programme designs that draw on empirically based best practises, and encourages adoption of evidence-based risk management strategies is becoming more and more important as the science of risk management develops. Through the development of more effective and efficient risk management techniques, more medications will have their benefit-risk profiles optimised, increasing patient safety.

Risk Management –

For the safe administration of pharmaceuticals and the defence of patient health, pharmacovigilance risk management is crucial. The four steps in the management of a single risk are risk detection, risk assessment, risk minimization, and risk communication. The risks connected with a typical pharmaceutical product will differ in terms of their seriousness, how they affect particular patients, and how they affect both individual and society health. Therefore, combining data on numerous dangers should be considered when thinking about risk management in order to make sure that the benefits outweigh the risks by as much of a margin as feasible, both for the individual patient and for the population as a whole.

Some drugs are banned in India because of the benefit-risk ratio. That are metamizole. It is nonsteroidal antinflammatory agent . Metamizole is banned in India in 2013.Side Effect – Bone marrow depression .Which reduce production of blood cells.

What is important in risk management

Risk Detection
Risk Assessment
Risk minimization
Risk communication

Steps Involved in Risk Management

Safety specification
Pharmacovigilance plan
Evaluation of the need for risk minimization activities.
Risk minimization plan.

safety Specification

summarised key risks that have been identified, key gaps in knowledge, demographics that may be at danger, and safety safety issues..
Helps identify the requirements for the pharmacovigilance plan's specific data collecting.

Pharmacovigilance plan

explains pharmacovigilance activities (regular and additional) and how to implement each safety plan when there is cause for concern. Process steps to address a safety problem have been identified. enhancing the methods used to identify safety alerts.

Evaluation of the need for risk minimization activities.

Discuss safety issues such as the possibility of drug errors and the requirement for regular or additional risk reduction measures. The need for additional risk-reduction measures over and above pharmacovigilance action plans is evaluated for each safety concern.

Risk minimization plan.

List safety concern for which risk minimization activities are proposed.. Discuss associated routine additional risk minimization activities and the assessment, of their effectiveness.

Risk Identification and Safety Specification

This is a summary of the significant known dangers associated with a pharmaceutical product, significant unknown risks, and significant knowledge gaps. Additionally, it highlights the populations that might be at risk and unanswered safety concerns that demand more research to improve comprehension of the benefit-risk profile during the post-authorization phase. outlines the various factors to keep in mind when gathering safety data throughout the non-clinical and clinical development of a biosimilar medication.
The security The Common Technical Document (CTD), particularly the overview of safety, benefits and hazards conclusions, and the summary of clinical safety, should be used as the foundation for issues identified in the safety specification.. The pharmacovigilance plan is typically used in conjunction with the safety specification, however parts of the safety standard can also be included in the CTD. During the postapproval period, clinical safety of comparable biological medical products must be thoroughly assessed on an ongoing basis, including ongoing risk-benefit analysis.

The risk minimization plan

The risk minimization strategy outlines the steps that will be taken to lower the risks connected to each specific safety concern. When a risk minimization plan is offered as part of an EU-RMP, it should comprise both standard and supplementary risk minimization actions. More than one risk-minimization activity may be linked to an objective for a safety concern. The safety issues that risk minimization activities are suggested to address should be listed in the risk minimization plan. It is important to talk about the risk-minimization efforts,

both regular and extra, connected to that safety concern. Additionally, a section outlining how the effectiveness of each suggested additional risk minimization activity would be evaluated should be included.

Monitoring of the safety profile

Signal Identification -

In the early stages of marketing, a lot of possible signals are likely to surface, therefore it's critical to properly assess them. If any of the following occur, it may be an indicator of potential unforeseen dangers or changes in the frequency, nature, or severity of expected adverse effects:

- the Marketing Authorisation Holders;
- the Rapporteur;
- the Agency in agreement with the Rapporteur .

The three main goals in Risk management are:

- Protect the patients
- Protect the Pharmaceutical Company
- Comply with regulatory Requirements

Conclusion

To develop an actionable RMP using a thoughtful, evaluative, science-based approach that considers all available evidence. As the science of risk management matures, the need for global harmonisation that reduces duplication of currently divergent approaches (e.g. reporting formats), leads to more effective programme designs that draw on empirically based best practices and encourages adoption of evidence-based risk management strategies is ever more critical. Such an approach will lead to the development of more effective and efficient risk management practices, resulting in optimised benefit–risk profiles for more drugs and improved patient safety**.**

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