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*Short communication*

# Structure, implementation and importance of risk minimization plan and risk minimization measures

Emilija Nikolovska[1*], Zorica Naumovska[2], Ljubica Shuturkova[2], Katerina Anchevska Netkovska[2]

[1]*Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia*
[2]*Ss. Cyril and Methodius University, Majka Tereza 47, 1000 Skopje, Republic of North Macedonia*

## Introduction

Information related to the safety profile of new medicinal products is based on data obtained during clinical trials, and therefore, at the time of obtaining marketing authorization, there is not enough information on long-term use of the medicinal product. Considering the limitations of the clinical trials, it can be expected that potential safety concerns may be identified in the post-authorization period, as wider use in real world setting provides additional information on the adverse effects that may occur with the use of the medicinal product (Lucas et al., 2022). The evaluation of the safety profile of a medicinal product is carried out throughout its entire lifecycle, through continuous evaluation of the risk-benefit balance and targeted activities for minimizing the identified risks. A wide range of mitigation activities can be carried out in order to minimize the potential risks while using the medicinal product. The proactive approach is important for early identification of safety issues and their timely management in quick and efficient manner. The aim of the risk management system for medicinal products is to ensure a positive benefit-risk balance for patients and the target population (Mouchantaf et al., 2021). The risk management system is a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent, or minimize risks associated with a medicinal product, including the assessment of the effectiveness of those activities and interventions. A risk management system encompasses the safety profile of a medicinal product, summarizes the identified risks, identifies potential risks, and defines further studies to be conducted after the approval of a medicinal product. The pharmacovigilance legislation that has entered into force in 2012 introduced more obligations, and defined the responsibilities of regulatory authorities and the pharmaceutical industry in the EU. Risk management plans became a mandatory requirement when applying for a marketing authorization of a medicinal product (Borg et al., 2015).

## Risk Management Plan

A Risk Management Plan (RMP) is a stand-alone document that the marketing authorization holder keeps updated throughout the life cycle of a medicinal product. The RMP defines the activities needed to increase the available information on the safety profile of the medicinal product and describes the measures to minimize the risks potentially associated with the use of the medicinal product (Butler et al., 2021). The RMP should be continuously updated throughout the lifecycle of the medicinal products and updates should be submitted when major changes occur: new indications, restrictions of the indication,

*emi_nikolovska@hotmail.com

new/updated contraindications, new important risks or important changes to known risks and any additional risk minimization measures, which is within the concept of continuous data collection, reporting and evaluation of the benefit-risk balance and determining any possible change in it (Borg et al., 2015).

## Risk Minimization Measures

Risk minimisation measures (RMM) are a set of actions that should be taken in order to reduce the risk of an adverse event occurring, or to reduce the harm from an event associated with a particular safety concern. The risks identified for a medicinal product are listed in the RMP. There are two types of RMM, routine and additional. Routine RMMs are activities that are implemented for each medicinal product, and include the summary of product characteristics, the patient information leaflet, the labeling (contraindications and warnings contained in the product information), the pack sizes and the legal status of the product. In cases where routine RMMs are considered insufficient to ensure the safe and effective use of the medicinal product, additional RMMs are required (Borg et al., 2015). Additional RMMs can be divided into safety and educational tools and risk minimization control tools. Educational tools for safety advice are addressed either to patients or to healthcare professionals and are intended to support adherence to the intended risk minimization activities. Educational and safety advice tools are risk minimization guides for patients or healthcare professionals (a healthcare professional risk minimization checklist, a risk awareness dialogue form, a patient card, a patient risk minimization diary, etc.) (European Medicines Agency, 2024).

## Future perspectives

In the future, the pharmacovigilance systems will focus on further increasing patient involvement and use of real-world data. Large amounts of healthcare electronic data can be processed with applying artificial intelligence techniques, machine learning and quantum computing, with aim to improve drug safety assessment. The potential for almost real-time identification of post-marketing adverse events, automatically performing tasks related to processing case reports, identifying groups of adverse events and relating them to symptoms, and predicting and preventing adverse events can be important advantages of using the artificial intelligence, machine learning and quantum computing in pharmacovigilance (Nagar et al., 2025).

## Conclusion

With the continuous development and integration of artificial intelligence, machine learning and quantum algorithms, pharmacovigilance is expected to become increasingly efficient and comprehensive. As a result, there is a potential for significantly advancing drug safety, with ultimate aim to improve patient health outcomes and contribute in public health enhancement (Naga et al., 2025).

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