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Literature Review: Risk management strategies in post marketing surveillance for drugs

Sattam M Alsokihy[1] Zafer A Alshihry[1] Mansour S Al sowayan[1] Turki A Almalki[1] Masalah S Almutairi[1] Abdulrahman A Alsaleh[1] Fahad N Alotaibi[1]

1 *Prince Sultan Military*
Medical City, Riyadh, SA.

Abstract

Post-marketing surveillance (PMS) plays a critical role in ensuring the safety and efficacy of drugs following marketing authorization. This review explores best practices and advancements in risk management strategies within the European context, focusing on key aspects such as optimizing risk communication, strengthening public engagement, and enhancing cross-border collaboration. Challenges such as data quality, ethical concerns, and balancing drug availability with safety are analyzed alongside the integration of digital tools, collaborative initiatives, and real-world evidence. Recommendations emphasize leveraging technology, harmonizing regulatory frameworks, and fostering patient involvement to enhance the effectiveness of PMS and safeguard public health.

Keywords: Risk management, post-marketing surveillance, Europe, pharmacovigilance, drug safety, public engagement, real-world evidence.

Introduction

The role of Post-marketing surveillance is critical in the lifecycle of drug products. The fact behind it is that it ensures continued evaluation of drug safety and efficacy after market approval. However, pre-market clinical trials is provid efficacy and valuable safety data that is limited by small sample sizes, short durations, and controlled environments (Deodhar & P. J. Mease, 2019). Secondly, post-marketing surveillance is also addressing these gaps properly through monitoring real-world drug use, ensuring patient safety on a broader scale, and identifying rare adverse effects .

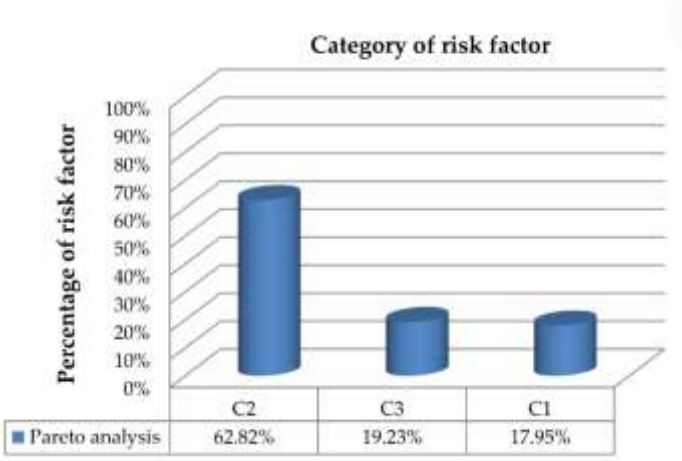

Figure 1: Risk factor category vs. percentage of risk factor

Table 1: Category of Risk factor vs. percentage of risk factor

Risk categories	C1	C2	C3
Percentage of risk factor	17.95%	19.23%	62.82%

This review is aiming to evaluate risk management strategies employed in post-marketing surveillance of drugs used in Europe. Moreover, it explores challenges, advancement, and best practices by drawing exclusivity gained from peer-reviewed journals for providing a robust and reliable knowledge base. This review synthesizes data gained from peer-reviewed literature published in a journal by focusing on regulatory environment of Europe (ElSayed & Grazia Aleppo, 2023).

Overview of Post-Marketing Surveillance (PMS)

Definition and Purpose

In one research, there is comprehensive information about the post-marketing surveillance. It is a vital mechanism for monitoring the safety, and efficacy of drugs when they are approved for public use (Alomar & Ali M. Tawfiq, 2020). The author defined PMS as the systematic collection, analysis, and interpretation of data regarding adverse drug reactions and other main safety concerns based on post-market phase of drug. Moreover, this phase is capturing data that pre-market clinical trials are unable to detect because of limited scope (Alomar & Ali M. Tawfiq, 2020). Another author showed that PMS is ensuring drugs to remain beneficial while resolving risks in real-world settings in which variability in drug and patient population interaction may reveal unforeseen issues (Badnjević & Lejla Gurbeta Pokvić, 2022).

Regulatory Framework for PMS in Europe

It can be noted that the European regulatory framework used for PMS is considered the most robust one globally and it is designed for protecting public health (Cioeta & Andrea Cossu, 2022). In this, the European Medicine Agency is extremely important in enforcing post marketing obligations for pharmaceutical companies (Cioeta & Andrea Cossu, 2022). According to this, one researcher discussed about Pharmacovigilance Directive 2010/84 EU that introduced some stringent measures to monitor drug safety including risk management plans, and mandatory pharmacovigilance systems (Siwan & Mukesh Nandave, 2024). Such directive is ensuring that the marketing authorization holders are involved actively in monitoring and reporting safety data. Another author highlighted the importance of EudraVigilance that is a centralized European database for ADR reporting and it is facilitating cross-border safety direction and risk minimization (Siwan & Mukesh Nandave, 2024).

Role of Risk Management in PMS

In PMS, risk management is considered an integral component. For this purpose, one author had noted that risk management involves identifying, evaluating, and mitigating main safety concerns for protecting public health (Rana & Danture Wickramasinghe, 2019). In Europe, RMPs are extremely important for new drugs and it outlines measures to detect and managing risks throughout a lifecycle of a product (Rana & Danture Wickramasinghe, 2019). This dynamic nature of RMPs is ensuring that they are continuously updated as latest safety data emerges. Hence, such proactive approach is allowing for targeted interventions like modifying product labels and restricting usage (Hristov & Riccardo Camilli, 2024).

Risk Management Strategies in Post-Marketing Surveillance

Pharmacovigilance Plans

It shows that pharmacovigilance plans are considered important tools for post-marketing risk management. In these plans, there is additional activities, and routine tasks aimed at detecting,

assessing and preventing ADRs (Narayanan & K. S. Lakshmi, 2020). From this, one author had described in detail about pharmacovigilance plans as structured frameworks that outline specific actions for monitoring safety. It includes some routine tasks like spontaneous reporting, and periodic safety update reports. These reports are analyzed to identify various trends (Narayanan & K. S. Lakshmi, 2020). However, some other activities like observational studies and targeted surveys that are used to address all identified safety concerns. Moreover, one author had emphasized on the importance of integrating patient-reported outcomes into pharmacovigilance plans for increasing data quality (Peters, 2021).

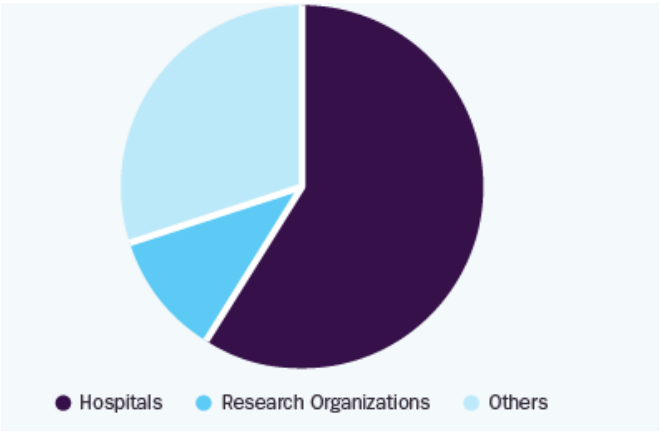

Figure 2: Post-marketing pharmacovigilance and medical information market

Risk Evaluation and Mitigation Strategies (REMS)

As it can be observed that all Risk Evaluation and Mitigation Strategies are originated in the USA and some similar concepts are implemented in Europe to address drug safety concerns. Based on one research that mentioned about risk mitigation strategies (Alomar & Ali M. Tawfiq, 2020). These strategies include drug distribution, the development of educational material for patients, and mandatory prescriber training material for patients (Deodhar & P. J. Mease, 2019). For this purpose, another author had discussed about the case of isotretinoin in which mandatory pregnancy prevention programs introduced. These programs were used to minimize teratogenic risks. All these measures are showing the importance of tailored risk strategies used for specific drug-related concerns (Peters, 2021).

Safety Communication and Education Programs

For risk management, effective communication is considered a cornerstone in PMS. Based on one author, that showed the importance of timely and transparent communication of drug risks to patients and healthcare professionals (Deodhar & P. J. Mease, 2019). Such communication can prevent harm and promoting informed decision-making. The author mentioned that direct healthcare professional communication, updates to protect labels, and safety alerts are common methods used in Europe (Deodhar & P. J. Mease, 2019). After this, the next author had noted that these initiatives are extremely effective when they include actionable and clear information tailored to various audience. Moreover, some digital platforms and social media platforms have emerged as vital tools for disseminating safety information (Deodhar & P. J. Mease, 2019).

Advancements in Risk Management for PMS in Europe

Integration of Digital Tools and Big Data

The efficiency of post-marketing surveillance systems in Europe is enhanced with the integration of big data and digital tools. According to one research, that showed the importance of digital tools like electronic health records, pharmacovigilance software, and wearable devices (Narayanan & K. S. Lakshmi, 2020). All these tools are allowing for the real-time collection and analysis of patient safety data. Moreover, these tools are also enabling earlier detection of adverse drug reactions and provide comprehensive insights into medication and use patterns in real-world settings (ElSayed & Grazia Aleppo, 2023). For this purpose, one author had highlighted the use of machine learning algorithms for analyzing large datasets that uncover hidden safety signals that were missed by traditional methods. Furthermore, another author had emphasized that by implementing big data, proactive risk management is supported through predicting main safety issues (Rana & Danture Wickramasinghe, 2019).

Real-World Evidence and Patient Registries

It can be noted that real-world evidence derived from patient observational studies, and registries as a vital asset in risk management for PMS. From this, one author had argued that RWW complements some traditional clinical trial data through providing long-term safety information to diverse populations (Badnjević & Lejla Gurbeta Pokvić, 2022). Moreover, in Europe, some initiatives taken like European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (Alomar & Ali M. Tawfiq, 2020). This initiative is used to promote the use of RWE to inform regulatory decision. Another author had showed how patient registries like those for rare disease are offering some valuable insights into medication adherence and effectiveness. All these registries are facilitating data linkage across various countries and enabling cross-border safety assessments (Hristov & Riccardo Camilli, 2024).

Collaborative Initiatives between Regulatory Bodies and Industry

The PMS efforts in Europe is strengthened by collaboration between pharmaceutical companies, regulatory authorities, and other stakeholders. From this, another author had described about public-private partnerships like the Innovative Medicine Initiatives foster the development of advanced pharmacovigilance tools and frameworks (Cioeta & Andrea Cossu, 2022). According to this, WEB-RADR project of IMI has explore the use of mobile applications and social media for ADR reporting (Narayanan & K. S. Lakshmi, 2020). Furthermore, the next research had highlighted that joint efforts streamline the implementation of Risk Management Plans to ensure a harmonized approach for drug safety across member states. These collaboration are encouraging the sharing of best resource and practices to enhance overall PMS efficiency (Alomar & Ali M. Tawfiq, 2020).

Challenges and Limitations in European PMS

Data Quality and Accessibility Issues

Beside these advancements, the quality and accessibility of PMS data is still a vital challenge. From this, one research had mentioned two main challenges like incomplete ADR submissions, and inconsistent reporting practices compromise the reliability of pharmacovigilance databases (Deodhar & P. J. Mease, 2019). After this, another research noted that there are some variations in healthcare across Europe is resulted in fragmented data collection and hinder cross-border harmonization. After this, another author had emphasized that due to lack of standardized reporting formats, the comparability of safety data issues is minimized across studies and countries (Narayanan & K. S. Lakshmi, 2020).

Balancing Drug Availability with Safety Concerns

It is reliable to balance the availability of innovative medicines with the need for rigorous safety monitoring pose a huge challenge in Europe. For this purpose, one author had highlighted that accelerated approval pathways like conditional marketing authorization can leave various gaps in safety data at the time of market entry (Deodhar & P. J. Mease, 2019). All these gaps necessitate robust PMS measures for ensuring ongoing risk assessment without delaying access to life-saving therapies of patients. Furthermore, another author had argued that these balancing acts may require some vital resources that can put a strain on pharmaceutical companies and regulatory bodies (Rana & Danture Wickramasinghe, 2019).

Ethical and Legal Challenges

It can be observed that there are some ethical and legal issues regarding to patient consent and data privacy present that put a huge impact on PMS in Europe. Hence, one research had provided information regarding the General Data protection Regulations that impose stringent requirements on the sharing, collection, and storage of patient data (Badnjević & Lejla Gurbeta Pokvić, 2022). Moreover, it also complicates pharmacovigilance efforts. After this, another author had noted that these regulations and put a delay on data-sharing agreements between stakeholders and minimize the timeliness of safety signal detection (ElSayed & Grazia Aleppo, 2023). Also, some ethical concerns arise when patients are not properly informed regarding the use of their data for PMS purpose. To address these issues, there is a need of a delicate balance between protecting individual rights and ensuring public health safety (Cioeta & Andrea Cossu, 2022).

Best Practices and Recommendations

Optimizing Risk Communication

It shows that effective risk communication is a main part of post-marketing surveillance in Europe. Based on one research, the author mentioned that transparent and timely communication ensure that healthcare patients and professionals are well-informed regarding potential risks to enable safer drug use (Narayanan & K. S. Lakshmi, 2020). It includes best practices like tailoring messages based on the requirements of diverse audiences by using non-technical, and clear language for patients with detailed scientific explanation for professionals. Furthermore, Direct Healthcare Professional Communication and updates are used to product labeling is still a critical tool. Furthermore, some recent advancements like digital platforms, and social media is providing some innovative channels to disseminate safety updates rapidly (ElSayed & Grazia Aleppo, 2023). For example, digital alerts are reliable to sue for notifying prescribers of emerging risk and it can be useful to improve responsiveness (Badnjević & Lejla Gurbeta Pokvić, 2022).

Enhancing Cross-Border Collaboration

For addressing safety concerns effectively, it is important to enhance strength of cross-border collaboration among European regulatory bodies (Deodhar & P. J. Mease, 2019). For this purpose, one researcher had noted that harmonized PMS systems like EudraVigilance is facilitating the sharing of pharmacovigilance data across member states to enable fast detection of adverse drug reactions. In includes some best practices like enhancing data interoperability, and standardizing reporting formats (Narayanan & K. S. Lakshmi, 2020). The next author mentioned about the collaborative frameworks like European Medicine Agency's Pharmacovigilance Risk Assessment Committee ensure consistency in decision-making, and safety evaluation across Europe. Lastly, enabling partnerships between various countries like audits and joint inspections can improve the efficiency level of monitoring processes (ElSayed & Grazia Aleppo, 2023).

Strengthening Public Engagement

In PMS, engaging the public is also a vital part for the success of risk management strategies. For this, one author had emphasized that empowering patients to report ADR can easily improves data quality level and foster a sense of shared responsibility for drug safety. Some public education campaigns are also reliable to enhance awareness of reporting systems (ElSayed & Grazia Aleppo, 2023).

Conclusion

Summing up all the discussion from above, it is concluded that the literature review, highlights the main role of risk management strategies in Post-Marketing Surveillance for ensuring efficacy and drug safety within Europe. There are some advancements include real-world evidence, digital tools, and collaborative frameworks have significantly strengthened pharmacovigilance systems. However, there are some challenges like ethical concerns, data quality, and balancing safety with drug availability persist. Some best practices like engaging the public, optimizing risk communication, and fostering cross-broader collaboration are important to address these challenges. By adopting these innovative approaches, and maintaining robust regulatory systems, Europe can increase the effectiveness of PMS and protect public health.

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