IMPLEMENTATION OF ACTIVE PHARMACOVIGILANCE SYSTEMS IN HEALTH SERVICES AND PHARMACEUTICAL INDUSTRIES: A CRITICAL ANALYSIS OF ANVISA'S REQUIREMENTS

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Abstract

This chapter aims to critically analyze the implementation of active pharmacovigilance systems in healthcare services and pharmaceutical industries in light of the regulatory requirements established by the National Health Surveillance Agency (ANVISA). A qualitative approach was adopted, based on documentary research and a narrative review of scientific literature and current Brazilian regulatory frameworks. The findings indicate that active pharmacovigilance represents a strategic advancement in the early detection of adverse events, enhancing patient safety and improving risk management processes. However, challenges were identified, including the standardization of procedures, professional training, integration of information systems, and the strengthening of a reporting culture within institutions. It is concluded that compliance with ANVISA's requirements requires not only regulatory alignment but also investments in clinical governance, health information technologies, and shared sanitary responsibility between public and private sectors.

Keywords: Active pharmacovigilance, ANVISA, Health regulation, Patient safety, Risk management.

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INTRODUCTION

The implementation of active pharmacovigilance systems has been consolidating as an essential strategy for strengthening patient safety and improving risk management within health services and pharmaceutical industries. In Brazil, health regulation is coordinated by the National Health Surveillance Agency (ANVISA), which establishes guidelines and normative requirements for monitoring, reporting, and analyzing adverse events related to the use of medicines. Unlike passive pharmacovigilance, centered on spontaneous reporting, the active approach involves systematic data searching, structured tracking, and the use of technological tools for early risk identification.

The research problem guiding this chapter consists of understanding how ANVISA's regulatory requirements influence the implementation and operationalization of active pharmacovigilance systems, considering the structural, technical, and organizational challenges faced by public and private institutions.

The general objective is to critically analyze the implementation of these systems in light of current regulations. As specific objectives, this chapter seeks to: (i) describe the main applicable regulatory requirements; (ii) identify barriers and potentialities in practical implementation; and (iii) discuss implications for patient safety and sanitary governance.

The justification for the study lies in the growing complexity of the pharmaceutical market, the expansion of access to medicines, and the need to strengthen post-marketing monitoring mechanisms. Active pharmacovigilance contributes to reducing underreporting, improving traceability, and promoting more assertive regulatory decisions.

From a theoretical standpoint, the debate is grounded in the concepts of health risk management, health surveillance, and shared responsibility among the State, industry, and care services. The literature indicates that effective pharmacovigilance systems depend on integration among regulation, health information technology, professional training, and an organizational culture oriented toward safety—indispensable elements for compliance with the guidelines established by the Brazilian health authority.

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METHODOLOGY

TYPE OF RESEARCH

This is a qualitative study, exploratory and descriptive in nature, with an analytical-critical focus. The research is grounded in a narrative review of the literature and documentary analysis of Brazilian health regulations related to active pharmacovigilance, especially those issued by the National Health Surveillance Agency (ANVISA). The choice of this design is justified by the need to understand normative, institutional, and operational dimensions that influence the implementation of pharmacovigilance systems in health services and pharmaceutical industries.

DATA COLLECTION PROCEDURES

Documentary research

Normative acts, Collegiate Board Resolutions (RDCs), technical guides, manuals, and guidance notes published by ANVISA were analyzed, with emphasis on regulations regarding Good Pharmacovigilance Practices and post-marketing monitoring of medicines. The documentary selection considered regulations in force up to the period of preparation of the chapter, prioritizing those directly applicable to marketing authorization holders and health services.

Literature review

The narrative review was conducted based on scientific articles, book chapters, and technical documents published in national and international databases. Descriptors related to active pharmacovigilance, risk management, patient safety, and health regulation were used. The analysis prioritized studies addressing implementation models, operational challenges, and regulatory impacts in Brazilian and international contexts.

CRITERIA FOR ANALYSIS AND INTERPRETATION

The collected material was subjected to thematic content analysis, enabling the identification of analytical categories, such as: regulatory requirements, organizational structure, reporting workflows, integration of computerized systems, and safety culture. Data interpretation occurred critically, relating theoretical evidence to normative requirements and institutional practices reported in the literature.

DELIMITATION OF THE DOCUMENTARY AND BIBLIOGRAPHIC SAMPLE

The documentary sample comprised exclusively federal regulations issued by ANVISA. The bibliographic sample included publications in Portuguese and English, prioritizing studies published in the last ten years, without excluding classic references considered fundamental for understanding the conceptual framework of pharmacovigilance.

METHODOLOGICAL FOUNDATION

The choice of a qualitative approach and documentary analysis made it possible to critically examine the coherence between regulatory discourse and its practical applicability. The adopted methodology allows discussion not only of normative compliance, but also of the structural, technological, and cultural challenges that influence the effectiveness of active pharmacovigilance systems. In this way, the methodological path ensures theoretical consistency and analytical rigor for the discussion proposed in this chapter.

RESULTS AND DISCUSSION

The documentary analysis of the regulations of the National Health Surveillance Agency (ANVISA), associated with the literature review, showed that the implementation of active pharmacovigilance in Brazil has advanced from a regulatory perspective, but faces significant structural and operational challenges in health services and pharmaceutical industries.

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Among the main findings, it stands out that Brazilian regulatory requirements converge with international post-marketing monitoring standards, reinforcing the need for structured systems for early detection of adverse events, risk management plans, and periodic safety reports. However, the literature points to gaps in the standardization of internal workflows and in the integration between care and regulatory sectors.

Table 1

Main regulatory requirements for active pharmacovigilance in Brazil

Regulatory Axis	ANVISA Requirements	Implementation Impacts
Structure	Appointment of a technical manager and a formal pharmacovigilance system	Need for a qualified team and clear definition of responsibilities
Active monitoring	Systematic search for adverse events and continuous safety assessment	Expansion of traceability and reduction of underreporting
Risk management	Preparation and updating of a Risk Management Plan	Integration among clinical, regulatory, and quality sectors
Reporting and deadlines	Submission of individual case safety reports and periodic reports	Operational demands and need for computerized systems
Audits and inspections	Documentary evidence and traceability	Strengthening the culture of regulatory compliance

The results show that adopting active pharmacovigilance contributes to greater sensitivity in risk detection when compared to traditional spontaneous reporting. However, reviewed studies indicate that

the effectiveness of these systems depends directly on organizational maturity and the incorporation of

information technologies.

Table 2

Main challenges identified in implementation

Category	Description of the Challenge	Repercussions
Professional training	Deficit of specific training in pharmacovigilance	Weakness in identification and causality assessment
Systems integration	Lack of interoperability between medical records and regulatory databases	Rework and data inconsistencies
Institutional culture	Underreporting and fear of accountability	Loss of relevant information for risk analysis
Financial resources	Limited investment in technology and specialized teams	Partial implementation of regulatory requirements

The discussion highlights that, although the normative framework is aligned with international

best practices, practical implementation remains heterogeneous. Scientific literature indicates that

countries with consolidated systems invest in process automation, data mining, and integration between

health surveillance and healthcare delivery.

Thus, it is observed that regulatory compliance is not limited to formally meeting standards, but

requires clinical governance, continuous monitoring of indicators, and strengthening of a safety culture.

Active pharmacovigilance, when effectively implemented, promotes not only compliance with ANVISA's

requirements, but also the consolidation of a preventive risk management model centered on the

protection of public health.

CONCLUSION

This chapter aimed to critically analyze the implementation of active pharmacovigilance systems in health services and pharmaceutical industries, in light of the regulatory requirements established by the National Health Surveillance Agency (ANVISA). Based on documentary analysis and literature review, we sought to understand how the normative framework influences the structuring, operationalization, and consolidation of these systems in the Brazilian context.

The main results showed that Brazil has a robust regulatory set aligned with international good practices, requiring a defined organizational structure, systematic monitoring of adverse events, preparation of risk management plans, and strict compliance with reporting deadlines. However, challenges were identified related to professional training, integration of computerized systems, budget limitations, and weaknesses in the institutional culture of safety and reporting.

As a contribution, this research offers a critical analysis that articulates regulatory discourse with the practical reality of institutions, highlighting that normative compliance, by itself, does not guarantee effectiveness. Investment in clinical governance, information technology, and continuing education is essential, as well as strengthening shared sanitary responsibility among the State, industry, and care services.

For future research, it is suggested to conduct empirical studies with field data collection to assess the maturity level of active pharmacovigilance systems across different regions of the country, as well as to investigate the impact of digital transformation and artificial intelligence on optimizing post-marketing monitoring processes.

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