**REVISTA CIENTÍFICA ACERTTE**
**ISSN 2763-8928**

# THE IMPORTANCE OF THE PERFORMANCE OF THE PHARMACOVIGILANCE SERVICE IN PROMOTING THE SAFE USE OF MEDICINES

## *A IMPORTÂNCIA DA ATUAÇÃO DO SERVIÇO DE FARMACOVIGILÂNCIA NA PROMOÇÃO DO USO SEGURO DE MEDICAMENTOS*

## *LA IMPORTANCIA DEL DESEMPEÑO DEL SERVICIO DE FARMACOVIGILANCIA EN LA PROMOCIÓN DEL USO SEGURO DE LOS MEDICAMENTOS*

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e52222
https://doi.org/10.63026/acertte.v5i2.222

PUBLICADO: 02/2025

**ABSTRACT**

Background: Pharmacovigilance occupies a prominent place after the event known as “the Thalidomide disaster”; several babies were born with malformations resulting from the teratogenic action of the drug in question, but before that, there had already been occurrences of damage in patients associated with the use of drugs. Objective: Promote a reflection on the importance of the performance of the pharmacovigilance service in the use of medicines. Methods: The study consists of preparing a prospective literature review on the most recent publications that address theoretical and practical concepts related to pharmacovigilance services in promoting the safe use of medications. Results: Risks will always exist with each new drug substance introduced on the market, but it is necessary to carefully evaluate each secondary outcome to identify the implementation of barriers and, thus, incorporate improvements in the processes that reduce negative events for the individuals assisted. Conclusion: The continuous development of health information technology can significantly improve patient safety, including innovative solutions, such as multiple strategies that prioritize integration through synergy, with the involvement of scientists, health professionals, and patients, whenever possible.

**KEYWORDS:** Pharmacovigilance. Medication safety. Risk assessment. Patient safety. Drug-induced damage.

***RESUMO***

*Introdução: A farmacovigilância ocupa lugar de destaque após o evento conhecido como “desastre da Talidomida”; vários bebês nasceram com malformações decorrentes da ação teratogênica do medicamento em questão, mas antes disso já havia ocorrências de danos em pacientes associados ao uso de medicamentos. Objetivo: Promover uma reflexão sobre a importância da atuação do serviço de farmacovigilância no uso de medicamentos. Métodos: O estudo consiste na elaboração de uma revisão bibliográfica prospectiva sobre as publicações mais recentes que abordam conceitos teóricos e práticos relacionados aos serviços de farmacovigilância na promoção do uso seguro de medicamentos. Resultados: Riscos sempre existirão a cada nova substância medicamentosa introduzida no mercado, mas é necessário avaliar criteriosamente cada desfecho secundário para identificar a implementação de barreiras e, assim, incorporar melhorias nos processos que levem à redução de eventos negativos para os indivíduos assistidos. Conclusão: O desenvolvimento contínuo da tecnologia da informação em saúde pode melhorar significativamente a segurança do paciente, incluindo soluções inovadoras, como estratégias múltiplas que priorizem a integração por meio da sinergia, com o envolvimento de cientistas, profissionais de saúde e pacientes, sempre que possível.*

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***PALAVRAS-CHAVE**: Farmacovigilância. Segurança medicamentosa. Avaliação de risco. Segurança do paciente. Danos induzidos por medicamentos.*

***RESUMEN***

*Antecedentes: La farmacovigilancia ocupa un lugar destacado después del evento conocido como "el desastre de la Talidomida"; varios bebés nacieron con malformaciones resultantes de la acción teratogénica del medicamento en cuestión, pero antes de eso, ya se habían presentado ocurrencias de daños en pacientes asociados al uso de medicamentos. Objetivo: Promover una reflexión sobre la importancia del desempeño del servicio de farmacovigilancia en el uso de medicamentos. Métodos: El estudio consiste en la elaboración de una revisión prospectiva de la literatura sobre las publicaciones más recientes que abordan conceptos teóricos y prácticos relacionados con los servicios de farmacovigilancia en la promoción del uso seguro de medicamentos. Resultados: Siempre existirán riesgos con cada nueva sustancia farmacológica introducida en el mercado, pero es necesario evaluar cuidadosamente cada resultado secundario para identificar la implementación de barreras y, así, incorporar mejoras en los procesos que conduzcan a la reducción de eventos negativos para los individuos atendidos. Conclusión: El desarrollo continuo de la tecnología de información en salud puede mejorar significativamente la seguridad del paciente, incluyendo soluciones innovadoras, como múltiples estrategias que prioricen la integración a través de la sinergia, con la participación de científicos, profesionales de la salud y pacientes, siempre que sea posible.*

***PALABRAS-CLAVE**: Farmacovigilancia. Seguridad del medicamento. Evaluación de riesgos. Seguridad del paciente. Daños inducidos por medicamentos.*

## 1 INTRODUCTION

The development of new drugs is not a simple process, as several stages are involved. It starts with identifying substances with potential characteristics to cause pharmacological activity. It is known that there are various sources of these substances, but what is important to know is that drug development involves rational planning (MIASSO, *et al*., 2010).

Pharmacovigilance can be defined as the science that encompasses activities related to identifying, evaluating, understanding, and preventing adverse effects related to the use of drugs. Thus, this service is responsible for monitoring the occurrence of adverse events related to drugs, intending to ensure that the benefits outweigh the possible harm caused by their use, always aiming at promoting the quality and safety of patients who use them.

In addition to adverse reactions to drugs, pharmacovigilance has the function of investigating other important factors, such as occurrences of quality deviation, and medication errors, including monitoring of unregistered drugs, intoxications, overdoses, and drug interactions. In this sense, pharmacovigilance also assumes responsibility for registering a new drug with Anvisa and ensuring its quality, efficacy, and safety. It is worth noting that these approval criteria are proven through clinical studies conducted according to predetermined scientific standards.

The problem is that these studies are limited, especially about the safety of using these products, as a limited number of individuals participate in these studies during a certain treatment time. This means that, after the start of drug commercialization, it is common to observe rare events

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resulting from prolonged exposure to the drug. For this reason, the pharmacovigilance system must be able to effectively identify all possible crises related to the use of each substance, to prevent possible harm to the health of patients.

As for the job market in pharmacovigilance, professionals specialized in this area tend to be highly valued, as their work is increasingly amplified in the pharmaceutical industry, where the best career and remuneration opportunities for these specialists are also found. It should be emphasized that this professional is also highly sought after for work in public careers, as there are several public service exams in government agencies, which represents another excellent option for those who wish to specialize in this field of work. For this reason, this specialist must have a multidisciplinary profile and in-depth and comprehensive knowledge of pharmacology, pharmacokinetics, and clinical pharmacy. It is worth including the need for competence to work in pharmaceutical care programs at various levels.

Once inserted in this career, the professional becomes responsible for contacting health authorities to ensure compliance with technical standards, including preparing reports and submitting safety information to regulatory entities through clinical risk analysis. In the case of hospitals, these professionals monitor the occurrence of adverse events, recording technical complaints, adverse reactions, and medication errors, as well as monitoring suspicions of therapeutic inefficacy. They also often propose local measures to control risks and damages in the environment where they work.

The purpose of this article is to promote reflection on the importance of the role of pharmacovigilance in drug use, namely, pharmacovigilance is conceived as *"the science and activities related to the identification, evaluation, understanding, and prevention of adverse events or any problems related to drug use"* (WORLD HEALTH ORGANIZATION, 2023)

This study is justified by the increase in population associated with other variables, such as unhealthy habits, which bring an increase in drug consumption. Health institutions have been encouraged to implement policies that aim to promote a culture of patient safety, where the goal is to reduce the number of adverse events during the patient's stay in the institution.

## 2 METHODS

This study is a prospective literature review. It is justified by starting from the principle of a guiding question, which serves as a guide for research, and the researcher, at the end of their work, answers this question, as proposed by the study's objective, based on literature searched in academic databases (CAMARGO; SILVA; MENEGUETTI, 2019).

A literature review is an investigation method that allows for the search, critical evaluation, and synthesis of scientific evidence available on a particular investigated theme, in which the product is the knowledge of the investigated theme, the implementation of effective interventions in care delivery

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and cost reduction, allowing the identification of weaknesses that may lead to the development of future investigations (Sousa, *et al*., 2017).

The research was divided into six stages: identification of the literature review's theme or questioning; sampling or literature search; categorization of studies; evaluation of studies included in the literature review; interpretation of results; and synthesis of the knowledge evidenced in the analyzed articles.

To select academic works, the following Portuguese descriptors were used: *farmacovigilância, evento adverso, and uso seguro de medicamentos*; and in English: pharmacovigilance, adverse event, and drug safety monitoring. To verify the theme's development during this period, data were collected from the following databases: CINAHL, LILACS, PubMed, Scielo, Scopus, and Web of Science between 2017 and February 2023.

To guide the research, the following guiding question was observed: What is the importance of the pharmacovigilance service's role in promoting the safe use of medicines?

## 3 RESULTS

The data collection was carried out and 306 published articles were found.

It is known that occurrences of adverse events related to medication use have been happening for many years. One of the events that drew attention occurred 169 years ago when young Hannah Greener from northern England died after receiving anesthesia with chloroform before the removal of an infected nail. The causes of Hannah's death were investigated to understand what happened, but it was not possible to identify what killed her. Her death was probably due to arrhythmia or broncho-aspiration. As a result of other deaths and alerts raised by doctors and the public about the safety of anesthesia, The Lancet Journal created a special commission to address this problem, requesting that English doctors, including those working in the colonies, report deaths caused by anesthetic procedures. The results were published in 1893 (KNIGHT; BACON, 2022).

The US Federal Food and Drug Act was created on June 30, 1906, and established that medications must be pure and free of contamination. This action was necessary since a high volume of food and drug adulteration and falsification had been identified (STROM; KIMMEL; HENNESSY, 2019).

In 1937, an elixir of sulfanilamide diluted in diethylene glycol caused the death of more than 100 people. The ingestion of this product resulted in renal failure in these patients. Since then, the Food and Drug Administration (FDA) has required various confirmatory tests for medication safety, including toxicity testing (STROM; KIMMEL; HENNESSY, 2019).

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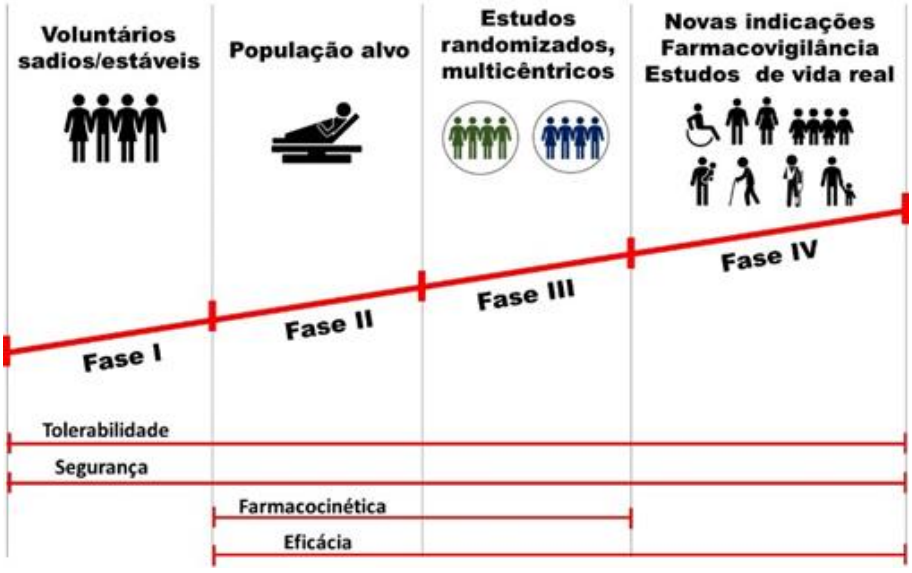
In the 1950s, it was noticed that the medication chloramphenicol was related to the occurrence of aplastic anemia. From then on, the focus turned to identify adverse reactions related to medication use (STROM; KIMMEL; HENNESSY, 2019).

It was in the 1960s that a milestone in patient safety history occurred, and the importance of having a service focused on identifying, evaluating, understanding, and preventing adverse effects related to medication use was realized. The event that occurred became known worldwide as the thalidomide disaster (STROM; KIMMEL; HENNESSY, 2019). This event was considered the most relevant medication for advancing health legislation and is considered the starting point for the concepts of pharmacovigilance and safety in health (MORO, INVERNIZZI, 2017).

After the commercialization of the medication thalidomide, cases of teratogenicity, i.e., congenital malformations caused by inadequate development of the bones of the arms and legs linked to normal growth of hands and feet, were identified. Brazil was the second most affected country in the world since the medication in question was indicated for the treatment of the disease known as leprosy. This event was of such importance that a specific law regulating its use in Brazil was created, Law No. 10,651 of April 16, 2003 (MORO, INVERNIZZI, 2017).

This event prompted various countries to implement adverse event tracking systems, and in 1968, the World Health Organization (WHO) developed a system whose goal was to collect notifications from national monitoring systems. For this purpose, the International Drug Monitoring Program (IDMP) was created (STROM; KIMMEL; HENNESSY, 2019). Since then, various processes have been installed in medication production, especially in the stages of testing and approvals. The implementation of the four phases in clinical trials was defined as mandatory, which are described below (SOCIEDADE BRASILEIRA DE PROFISSIONAIS EM PESQUISA CLÍNICA, s.d.):

**Figure 1**. *Description of the phases that make up the clinical studies.[6]*



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● Phase I: Pharmacokinetic and pharmacodynamic studies begin. Since these are clinical trials, this is the first phase where studies are conducted in humans. In this case, healthy volunteers are used, so the efficacy of the drug is not evaluated in this stage. Generally, this phase provides information on safety and preliminary information on the effect. The number of volunteers in this phase is around one hundred people (MIASSO, *et al*., 2010).

● Phase II: Aim to demonstrate the activity of the drug in a population that has the disease of interest. The number of volunteers is more restricted than in Phase I, as it works only with a select group of patients with the disease under study. In this phase, data related to safety and effects are still discussed, but now with more specificity. Data collection on the efficacy of the drug begins. Usually, these studies are already conducted in hospitals with the necessary infrastructure for patient monitoring.

● Phase III: Similar to Phase II, but the number of people studied exceeds one thousand. In this stage, work begins on collecting suspected adverse reactions to the studied drug. Comparison parameters are usually based on the use of the drug versus the placebo. Studies in this phase are part of the documents required to request new drug registrations.

● Phase IV: Known as pharmacovigilance. This stage considers monitoring activities in post-commercialization. It is the object of study of the present work and will be widely discussed.

Phase IV studies are important because they involve the expanded use of a drug in the population, which leads to various events as exposure to the drug increases. Through these reports and studies, suspected adverse drug reactions are updated (MIASSO, *et al*., 2010).

To ensure patient safety, in conjunction with Phase IV studies, it is important to develop government agencies to monitor the risk versus benefit relationship of marketed drugs. The International Drug Monitoring Programme is coordinated by The Uppsala Monitoring Centre in Sweden (MIASSO, *et al*., 2010). This system is capable of gathering notifications made by the countries that make up the group of notifiers. Only in 2001 did Brazil join this group and currently the PIMM is made up of 120 countries (STROM; KIMMEL; HENNESSY, 2019).

In Brazil, pharmacovigilance began after the thalidomide event, but the initial actions were not very successful. The National Drug Policy was approved in 1998, which aims to promote the safety, efficacy, and quality of drugs. The publication of this document was the starting point for pharmacovigilance actions (RIGO; NISHIYAMA, 2005).

In terms of legislation, pharmacovigilance was implemented in Brazil with Law 9,782 of 1999, which created the National Health Surveillance Agency (Anvisa) to establish, coordinate, and monitor toxicological and pharmacological surveillance systems. In 2001, Anvisa's Pharmacovigilance Unit

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(Ufarm/Anvisa) and the National Centre for Drug Monitoring were created. In the same year, Brazil became the 62nd country to become a member of the WHO Pharmacovigilance Programme. Anvisa's specific unit creation included the development of Regional Centers in partnership with state VISAs, universities, and other institutions that analyze drug safety, the promotion of continuous education within the sector, and the creation of the Sentinel Hospitals Network, which focuses on safe use and drug surveillance, including the accreditation of Notifying Pharmacies.

The Sentinel Hospitals Network was one of Anvisa's strategies for collecting adverse events (STROM; KIMMEL; HENNESSY, 2019). One hundred national hospitals were selected to monitor the quality and safety of patients treated. The selection criteria were the number of beds and the number of medical residency programs. These hospitals will not only address pharmacovigilance, but also technovigilance, hemovigilance, surveillance of sanitizers, and hospital infection control (CHAGAS, 2013).

### 3.1 Pharmacovigilance

Pharmacovigilance is defined as the science that encompasses activities related to the identification, evaluation, understanding, and prevention of adverse effects related to the use of medicines. This service is responsible for monitoring the occurrence of adverse events related to medicines, ensuring that the benefits outweigh the possible harm caused by their use, to ensuring the quality and safety of patients who use them (BENINGER, 2018).

Although clinical trials identify various adverse effects, they are still insufficient to determine all the risks associated with using medicines. Monitoring of possible harmful effects should certainly occur throughout commercialization to obtain information related to the new impacts, as exposure to the drug occurs on a larger scale. Thus, the number of events also increases especially serious events (MIASSO, *et al*., 2010).

In this scenario, medicines should be seen not only as drugs, excipients, and adjuvants but also as products participating in a process where the incorporation, technical and intrinsic qualities of the medicine associated with communication and continuous team training occur to promote the safe use of medicines (MIASSO, *et al*., 2010).

Certainly, pharmacovigilance systems have gained greater breadth and efficiency with the incorporation of new information technology and analysis. It is worth noting that in the last decade, there has been a growing awareness that the scope of pharmacovigilance should be extended beyond the rigid limits of identifying new signals related to safety. With globalization, consumerism, the explosion of free trade, communication between borders, and the increasing use of the Internet, there has been a structural change in access to all medicines and information about them. These changes have given rise to new types of safety-related issues, such as the illegal sale of medicines and drugs of abuse on the Internet, the growing practice of self-medication, potentially unsafe and

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irrational donation of medicines, widespread manufacture and sale of counterfeit and low-quality medicines, and the increasing use of traditional medicines outside the scope of the culture of the traditional use of medicinal plants with other medicines with the potential for adverse drug interactions.

Thus, there is a need to reconsider the practice of pharmacovigilance, given the lack of a clear definition of the boundaries between food, and medicines, including traditional, herbal, and "natural" products, health products, and cosmetics. The growing public expectation of safety regarding all these items also adds another dimension of pressure for change, as national pharmacovigilance centers are not in a position to deal with all the issues associated with pharmacovigilance alone. Recently, this field of activity has been expanded to include herbal medicines, traditional and complementary medicines, blood products, biological products, health products, and vaccines.

### 3.2 Adverse Drug Reaction (ADR)

ADR is any unintentional harmful response to a drug that occurs in the doses normally used in humans for prophylaxis, diagnosis, and treatment of disease or modification of physiological function (WORLD HEALTH ORGANIZATION, 2012) In others words, it is damage caused by the intrinsic properties of the drug (MIASSO, *et al*., 2010).

The most used way of classifying ADRs is that which determines whether they are dose-dependent (type A) or dose-independent (type B). Type A is characterized by having effects expected from the use of the drug. These are high-incidence and low-risk life. Type B, on the other hand, are unexpected and pharmacologically unpredictable, therefore, they are of low incidence but a high risk to life (MIASSO, *et al*., 2010).

### 3.3 Deviation of Quality of Medicines (DQ)

According to RDC 210/03, DQ is any deviation from the standards of quality expected for a given product, in this case, medicines, which may result in a health risk (AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA, 2008). Quality deviation can occur between stages of manufacture, transport, or storage, the most observed being: alterations in the organoleptic characteristics (color, odor, and flavor), failure in the filling of primary packaging (missing tablet in the pod or more than one unit per pod, broken pills or in different formats than expected (ROSA, 2013).

### 3.4 Medication Errors

According to WHO, a medication error is

> Any preventable event that may cause or lead to inappropriate use of medication or harm to the patient while the medication is under healthcare professional, patient, or consumer care. Such events may be related to professional practice, products, health systems, and procedures, including prescribing, communicating among professionals, labeling, packaging, nomenclature, composition, dispensing, distribution, administration, education, monitoring, and use (NATIONAL

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COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING AND PREVENTION, s.d.).

Medication errors can occur at any stage of the medication chain and can increase patients' length of stay in health institutions, which is closely associated with rising costs (VILELA, *et al*., 2018).

In 1997, a study was carried out that aimed to evaluate the additional resources necessary associated with Adverse Drug Events (ADE). The result of the study presented a potential cost of US$ 5.6 million per year, of which US$ 2,595.00 per event and $4,685.00 worth of preventable events (BATES, *et al*., 1997).

This same theme was emphasized in 1999, after the American report *To Err is Human: building a safer health system*, which had an estimated death of 44,000 to 98,000 people as a result of medical errors that could have been prevented, thus representing a potential cost of US$ 2.8 million per year (KOHN; CORRIGAN; DONALDSON, 2000). Among the published information, one of the characteristics described is that 60% of reported adverse events occurred in the period between 7 am and 7 pm (important highlight that these are the times with the greatest flow and movement in hospitals) (INSTITUTO BRASILEIRO DE SEGURANÇA DO PACIENTE, 2000).

## 4 DISCUSSION

The use of drugs has increased over the last few years and, therefore, the number of people exposed has been increasing. They must be kept under surveillance, exacting standards equal to the drugs in development and under evaluation, and prescribing habits, the extent of use rational and cost-effective are reviewed periodically. It is worth mentioning that scientists, prescribers, Pharmaceutical Industries, regulatory bodies, and also those responsible for creating and maintaining public policies, as well as such as patients and the general public, have their roles to play so that we can ensure that pharmacovigilance gets the expected result, that is, the reduction of damage to the health of society.

In this process, we can observe that the most important questions are related to information, information sharing, and communication more comprehensively. That's why we need to ensure a development dynamic and ongoing process of modern professional practice in health care, recognizing that solutions to challenges must come from individuals and institutions worldwide, inspired and committed to a modern vision and improved patient safety. In this undertaking, it is up to the spirit of collaborative sharing of information and intelligence to be in tune with the vision and the aspirations of the Declaration of Erice, proclaimed in September 1997, when gathered in Erice, Sicily, diverse representatives of the scientific sectors, economic and social, involved in monitoring, evaluation and drug safety communication, including healthcare professionals, researchers, members

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of the media, the pharmaceutical industry and regulatory bodies, in addition to patients, consumers, lawyers and of international organizations related to social welfare.

According to several researchers, Pharmacovigilance can be considered as part of the Sanitary Surveillance System, which had its configuration historically linked to the containment of epidemics and is part of the history of several countries and the framework of functions of public power since the earliest times remote.[18] In Brazil, the structure of Sanitary Surveillance started in the 18th century, aimed at controlling the salubrity of water and cities, the practice of barbers, apothecaries, and surgeons, the circulation of goods and people, with their organization and functions with characteristics of sanitary police, inspection and punitive. But from the Industrial Revolution and mainly after the second half of the 20th century, with the accelerated development of the industrial medical complex, we have an increase in the possibility of cure, prevention, and control of several diseases, with the world witnessing the introduction of new forms of production, circulation, and consumption of goods and services (ROZENFELD; MATOS; NASCIMENTO, 2007).

According to Nascimento, Rozenfeld & Matos18, these new products and services also bring risks, as such amenities can present uncertainties and dangers. Like this, new challenges arise for health surveillance, in the field of regulation of relations between production and consumption. However, they agree that for this definition, the functions of Pharmacovigilance are not restricted to adverse reactions, because the problems with medicines under your responsibility also cover quality deviations, medication errors, loss of effectiveness, use of drugs for unapproved indications, including acute intoxication or chronic illness, medication abuse, drug-substance interactions chemicals, among other medicines, and even food. Still, given these authors, we can say that both prevention and precaution must be manifestations of care, as precaution imposes the obligation of vigilance in the face of the fear of harm, including the preparation of the decision, the way to act, and the follow-up of the consequences.

Taking these aspects into account, we can say that Sanitary Surveillance is focused on risk regulation as a process, which encompasses management, analysis, and communication. The areas of risk regulation are four: that of products, including food, medicines, cosmetics, sanitizing products, and others of health interest; the services of health and in the interest of health; that of environments, including work; and finally, the area of movement of goods and people. Pharmacovigilance is related to the risk associated with the use of drugs in environments hospitals or where there are potential risks or threats of harm to individual health or public health regarding efficacy, safety, quality, or medication information.

It is worth mentioning that the actions of health surveillance of medicines cover the entire life cycle of these products, even before production to consumption and their effects, evaluating the efficacy and safety of drugs in the pre-registration phase, relating to pre-clinical and clinical trials, in addition to continuously monitoring the effectiveness and safety of drugs in the post-marketing phase

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as an essential tool for the well-being of society that uses these products to improve health and, consequently, quality of life.

## 5 CONSIDERATIONS

We can see that for all drugs there is a relationship between the benefits and the potential for harm. To minimize these damages, it is necessary that drugs of good quality, safety, and efficacy are used rationally and that the patient's expectations and concerns are taken into account when therapeutic decisions are made. Reaching this level means serving the health public and feeding patients' sense of confidence in the medicines they use, in the assistance team, extending this feeling to the services of health care in general. Pharmacovigilance has developed and will continue to develop in response to special needs, guided by the specific strengths of WHO Program members and beyond them.

This review found evidence that it is possible to reduce harm to patients when there is action by the pharmacovigilance service with a focus on the appropriate process conducted by a multidisciplinary team.

Our review also highlighted evidence gaps related to the occurrence of adverse events in general and what were the barriers implemented to help to reduce events. Therefore, further studies are needed for experimental and quasi-experimental tests before deciding the best strategy to be enlarged. In this sense, it is necessary to find the most impactful interventions in the attempt to reduce medication errors through theories and practices capable of comparing them across different settings and stratified populations to include the more critical information for both patients and healthcare systems in future undertakings.

It is up to researchers to use validated frameworks for drugs to standardize outcome measures. The intention, in this case, is to reduce adverse events in their different configurations. As well as the continuous development of health information technology can significantly improve patient safety, other innovative solutions such as multiple strategies that prioritize synergy, including patient engagement whenever possible, also deserve to be evaluated with due attention.

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**REVISTA CIENTÍFICA ACERTTE**
**ISSN 2763-8928**



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