

## Pharmacovigilance: “Vigilantia initiative”

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Every day Pharmacovigilance becomes increasingly important to patient health. There are some gaps and limitations in the current Latin American Pharmacovigilance framework which could be addressed to have a better system to correctly and promptly identify suspected adverse drug reactions (ADR). Considering this context, Vigilantia was born as an initiative to foster Pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, across all Latin America.

Keywords: Pharmacovigilance, patient safety, Vigilantia, adverse drug reaction (ADR)

### 1. Introduction

Pharmacovigilance becomes more important to patient health every day. According to the World Health Organization (WHO), pharmacovigilance plays an important role in protecting patient safety by identifying, quantifying, assessing and preventing risks that arise from the use of medicines. It is a discipline that learns from its own experience, evolves and is re-defined with the arrival of new research data and results. The overall goal of Pharmacovigilance is to accurately and promptly trace a patient’s adverse event to a particular product and manufacturer and to use this information to improve public health by ensuring a positive benefit risk profile for the medicine [1].

According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), all biopharmaceutical companies, countries and national regulatory authorities should have appropriate controls and measures in place to perform this important discipline. Recently, the scope of pharmacovigilance has expanded to overlap, in part, with additional activities such as the need to monitor possible counterfeit medicines, the development of good manufacturing practices and the training of healthcare professionals (physicians, pharmacists, and nurses) and stakeholders in good pharmacovigilance practices [2].

All medicines can cause adverse drug reactions (ADR) and certain rare ADRs, undetectable during clinical trials prior to marketing authorization, which are only

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discovered once the medicine is on the market. Moreover, there are some key pharmacovigilance principles to ensure biotherapeutic medicines safety that are important to discuss further. It is critical to manage biotherapeutic medicines correctly because they have unique characteristics. Due to their biological nature and complex structure, biotherapeutic medicines require special ADR tracking. Traceability is vital for correct biotherapeutic management, and for this there has to be a distinguishable name, safe prescription and dispensing to patients, and accurate reporting of suspected ADRs. Prescribing by brand name and distinguishable International Nonproprietary Name (INN) allows physicians rapid access to the precise product dispensed when reporting suspected ADRs.

However, good tracking and tracing practices are not enough for an effective application of pharmacovigilance. It is critical to have a good and well-structured system that facilitates ADR reporting from all sources, including patients and healthcare professionals. In addition, it is also important for some medicines to have a Risk Management Plan (RMP) that proactively plans activities to characterize known risks, identifies new risks, drives increased knowledge about the safety profile of the medicine, and plans and implements risk minimization and mitigation if appropriate. Nevertheless, traceability and an adequate system will be useless if the stakeholders involved do not use these tools adequately. Healthcare professionals should use distinguishable names when prescribing a medicine and key stakeholders should report ADRs in a consistent way to ensure effective pharmacovigilance monitoring [3].

There are some gaps and limitations in the current status of pharmacovigilance in Latin America that could be addressed to have a better system to correctly and promptly identify ADRs. Considering this context, Vigilantia was born as an initiative to foster pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines across all Latin America. Vigilantia focuses on three main pillars: 'Pharmacovigilance Training in a Box', a strategic alliance with ISoP (International Society of Pharmacovigilance), and the Peers and Voice initiative. These pillars are further described in this article.

## **2. Background information on pharmacovigilance in Latin America**

The article "Key elements in the establishment of adverse events notification systems in Latin America" from Mira JJ, Cho M, Montserrat D, Rodríguez J, Santacruz J. describes the results of a study which took place in seven Latin American countries (Argentina, Brazil, Chile, Colombia, Cuba, Mexico and Peru) with 17 national experts on adverse event notification and three experts from the Pan American Health Organization (PAHO). In this study the authors analyzed the main characteristics, scope and limitations of the adverse event notification systems in the region [4].

From the study it can be concluded that in Latin America there is a lack of basic pharmacovigilance knowledge among health professionals which means they do not have the necessary background to complete and submit quality suspected

ADR reports. Furthermore, there is no tradition of prioritizing patient safety in Latin America so it is difficult to engage healthcare professionals in pharmacovigilance. These findings show a clear need for improvement of the suspected ADR notification system, focusing on training healthcare professionals on the process [4].

Moreover, IFPMA, in its report "Pharmacovigilance of Biotherapeutic Medicines: Identifying Global Case Studies Illustrating Successes and Challenges" shows that countries like Mexico have been working in developing new systems to engage and encourage patients to report ADRs. This real-life example demonstrates that reporting by patient groups has the potential to increase knowledge about the possible harms of medicines increasing patient's safety [2].

Another important example in IFPMA's report focuses on Brazil, which has adopted patient registries as a post-marketing surveillance tool. BIOBADAMERICA is a tool that collects information on relevant adverse events occurring with long-term treatment with biotherapeutic medicines. This platform allows for continuous online monitoring and facilitates the interaction between pharmacovigilance monitors and collection centers [2].

Hence, there is a clear consensus that all Latin American countries should establish a certification program in order to train experts such as healthcare professionals, academics and regulators, and all stakeholders who might be involved in the process of ADR reporting in basic pharmacovigilance. The successful implementation of new and better pharmacovigilance systems depends on healthcare professionals and national regulatory authorities that are trained in the need, value, and operation of the country's pharmacovigilance system [1].

### **3. Vigilantia**

Vigilantia is an initiative that emerged to respond to the need to improve the Pharmacovigilance process in Latin America. Vigilantia aims to raise awareness and stimulate interest in the importance of patient safety and provides a walk-through of the current Pharmacovigilance practice as well as a description of other related pharmacology topics. The core purpose of this initiative is to stimulate the full and proper use of national ADR reporting systems by training and informing all relevant stakeholders on best practices to protect patient safety.

Vigilantia consists of three main pillars: 'Pharmacovigilance Training in a Box', ISO-P Collaboration and Peers and Voice.

### **4. Pharmacovigilance training in a box**

After careful study, IFPMA concluded in its report that the initiatives to improve pharmacovigilance are only useful if the quality and quantity of the ADR reports are adequate. Therefore, to provide high quality reports, it is key to have healthcare

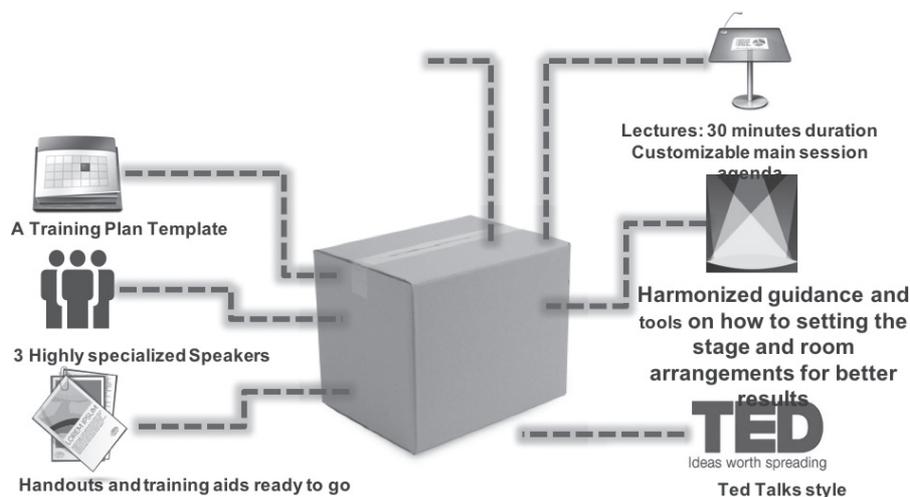


Fig. 1. PV Training in a box. Is the best quality I have, if is not good please remove it.

professionals and other interested stakeholders that understand the importance of pharmacovigilance to patient safety and that adequately report ADRs in a timely manner to improve the quality of information and reporting rates [2].

Pharmacovigilance Training in a Box is an effective training toolkit on basic Pharmacovigilance, modularly assembled as a "One-Size-Fits-All" training to satisfy different stakeholders with a 1-day training session. Figure 1 shows the components of the training kit. The material is clear, concise and interactive which allows any stakeholder to learn the basic aspects of pharmacovigilance in 1 day.

The training comprises two modules: Vigilantia I, which is concerned with basic pharmacovigilance issues; and Vigilantia II, which addresses new concepts related to medicinal products such as biotherapeutic and biosimilar medicines, and the application of pharmacovigilance to this newer category of medicines.

Each segment comprises two chapters: one theoretical and the other practical. The aim of the first chapter is to familiarize stakeholders with pharmacovigilance as a tool for successful medicine management and to educate participants in specific considerations for medicinal products such as biotherapeutics and biosimilars. In the second chapter, the training participants have the opportunity to apply the theoretical knowledge they have learned in the first chapter by discussing real-life experiences and defining positions.

Likewise, Vigilantia II has a theoretical segment where stakeholders learn about innovative biotherapeutic and biosimilar medicines, and the strong link to pharmacovigilance. The practical segment facilitates a space for discussion about the different topics learned.

The Vigilantia Pharmacovigilance Training in a Box is a toolkit that aims to educate stakeholders about pharmacovigilance and its applications in an interactive way.

## **5. Partnership with ISoP**

ISoP is a key partner in the Vigilantia Initiative, and its collaboration has been crucial. In 2009, ISoP created its Latin American Chapter with the objective of developing educational activities with the aim to increase knowledge and to ensure training in the field of pharmacovigilance [5].

Since 2014, ISoP has organized annual meetings, co-sponsored by FIFARMA, to discuss different pharmacovigilance topics. The main objective of these meetings is to foster pharmacovigilance in Latin America by inviting key stakeholders in pharmacovigilance to discuss relevant topics.

Since the creation of Vigilantia there have been two Latin American ISoP symposiums (both supported by FIFARMA). The first one was held in Buenos Aires in 2014 and centered on "Keeping our focus on what matters to patients". The key message of this symposium was "to have a real impact on patient welfare and safety, pharmacovigilance must be an integral part of the healthcare delivery system and also seen as a matter of critical importance for the whole of society".

The second Latin America ISoP symposium took place in Sao Paulo, Brazil in September 2015. This symposium focused on providing a space for multiple stakeholders to discuss drug safety and signal detection from different perspectives to share ideas on how patient safety could be further improved. The scientific program, coordinated by Raquel Herrera Comoglio, was a well-balanced combination of the fundamental basics and practice of pharmacovigilance, as well as the most recent challenges in drug regulation and use [5].

The third Latin American ISoP Symposium will be held in Bogotá, Colombia on August 25 and 26, 2016.

## **6. Peers and Voice**

Peers and Voice is a scientific network with the objective of addressing and amplifying pharmacovigilance topics that have become more of a challenge for healthcare professionals, payers, national regulatory authorities, scientific organizations, universities, state authorities, patient groups and the pharmaceutical industry.

Peers and Voice was created to pioneer pharmacovigilance education and reinforce the need to implement risk management plans for medicines. Peers and Voice is a network that aims to expand pharmacovigilance awareness to diverse types of stakeholders, from consumer groups to NGOs. In January 2016 a strategic "call to action" workshop was held in Buenos Aires with key stakeholders and selected professionals from different regional associations whose objective was to share the Vigilantia Pharmacovigilance Training in a Box materials and to plant the first seed of the Peers and Voice initiative. One of the main results of this meeting was the formation of four working groups led by regional associations with the objective to develop specific projects and key tasks for Vigilantia in each region or country.

## 7. Conclusions

It is clear from this article that pharmacovigilance has become an essential tool to protect patient safety. Everyone should understand the value of reporting and monitoring suspected medicine side effects. Latin America does not have a robust system that facilitates the submission of high quality ADR reports in the region. Therefore, Vigilantia emerges from a need for new or better systems to report suspected ADRs as well as a need to improve regional pharmacovigilance processes. Thus, Vigilantia aims to address these challenges by training key regional stakeholders on good practices to improve patient safety.

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