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Review

Saudi Vigilance Program: Challenges and lessons learned

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ABSTRACT

Pharmacovigilance is vital to public health. Adopting a robust spontaneous reporting system for adverse drug events can counteract most hazards that arise from utilizing medicinal products. Prior to the establishment of the Saudi Food and Drug Authority (SFDA), the number of pharmacovigilance-related activities in Saudi Arabia was limited. In 2009, the SFDA established the National Pharmacovigilance and Drug Safety Center (Saudi Vigilance). The pharmacovigilance system has remarkably improved during the past few years. Several initiatives have been taken to improve the program's performance. These initiatives include initiation of pharmacovigilance guidelines, enhancement of communication and reporting tools, training sessions for concerned staff and healthcare providers, and compliance from stakeholders. This review article provides an overview of what the Saudi Vigilance program is, focusing on the scope, mission and vision, hierarchy, operational themes, and overall work processes. Additionally, we will shed light on the challenges we encountered during the early phase and on our future plans.

Contents

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1. Introduction

The Saudi Food and Drug Authority (SFDA) was established as an independent body in 2003 to regulate food, drugs, and medical devices as well as set necessary regulations and specifications for both imported and locally manufactured products. Prior to the SFDA's establishment, most regulations related to these products were created by different ministries in Saudi Arabia, such as the Ministry of Health (MOH), Ministry of Commerce, Ministry of Municipality, and Ministry of Agriculture. Basically, the SFDA consists of three major sectors: the drug, food, and medical devices sectors. All three sectors are equipped with highly competitive technical associates and robust information technology systems.

One of the drug sector's main tasks is to establish a suitable regulatory framework to monitor the risk-benefit balance of all registered products throughout their life cycles in the Saudi market. Therefore, the SFDA has established a pharmacovigilance system that operates under the National Pharmacovigilance and Drug Safety Center (NPC). The process of establishing the Saudi pharmacovigilance system, the challenges of implementing it, lessons learned, and more will be described in this paper.

2. Pharmacovigilance activities prior to the establishment of the SFDA

The earliest program for adverse drug event (ADE) reporting was established in 1975 as a hospital-based program at King Faisal Specialist Hospital and Research Center in Riyadh. In 1998, the MOH in Saudi Arabia established a post-marketing program, which focused mainly on early detection of unexpected and serious adverse drug reactions (ADRs), detecting increases in frequency of known ADEs, identifying quality defect issues of registered products, and disseminating necessary safety information. A training program was carried out in collaboration with the United States Food and Drug Administration (USFDA) in the main regions of Saudi Arabia. The program was launched in the main hospitals and private community pharmacies, and ADE reporting forms were dispatched to those institutions. In addition, a national database for aggregating received ADEs was initiated in 2002, and in 2003, an advisory committee was assigned to oversee, study, and classify ADE reports and other drug safety issues. Unfortunately, the program suffered from a lack of staff and technical support (Bawazir, 2006).

3. Legal basis for pharmacovigilance activities

The legal framework for pharmacovigilance of pharmaceutical products for human use in the community is given in the law of Pharmaceutical Institutions and Pharmaceutical Products number M/31 (Saudi Council of Ministers, 2005) as well as Council of Ministers directive number 168, dated September 2, 2002. These laws described the respective obligations of the marketing authorization holders (MAHs) and the national regulatory agency in Saudi Arabia to set up systems for pharmacovigilance to collect, collate, and evaluate ADEs and take the appropriate regulatory corrective actions to mitigate the risks certain medicines pose. The regulations required that the MAHs and national regulatory agency share all available information related to drug safety and effectiveness to ensure favorable risk-benefit balance of marketed pharmaceutical products.

To facilitate compliance with these obligations, the SFDA developed pharmacovigilance guidelines to describe the roles and responsibilities of all relevant stakeholders. These guidelines were developed by a committee that included representatives of a variety of Saudi institutions, such as the MOH, universities, and tertiary hospitals, to ensure involvement of different stakeholders. To cope with global harmonization efforts, the regulations implemented were based on the guidelines of the International Conference on Harmonization (ICH) and the European Medicine Agency (EMA) (European Commission, 2008). When the guidelines were being developed, interested entities including MAHs were given the opportunity to provide feedback concerning the beta version of the guidelines. That stage was deemed a fine-tuning period prior to the guidelines' final implementation and adoption in 2009.

The SFDA officials believed that involving of all stakeholders in guideline development was important to initiating a solid, well-built pharmacovigilance system, even though the pharmacovigilance concept was relatively new to many MAHs with limited capabilities at that time. Because of capacity limitations, some companies expressed concern about implementing certain requirements. For example, obeying technical requirements for individual case safety reports (ICSRs) submission, such as generating XML-E2B files, was especially challenging for small and local companies. Therefore, during the transitional period it was acceptable to submit ICSRs using the Council for International Organizations of Medical Sciences (CIOMS) (Faich et al., 1990) format.

To facilitate the process of establishing a pharmacovigilance system, the guidelines emphasized the role of a qualified person responsible for pharmacovigilance (QPPV). Each MAH was asked to nominate a QPPV residing within the Kingdom of Saudi Arabia who would be responsible for the establishment and maintenance of the pharmacovigilance system. The legislations stated that a QPPV should be appropriately qualified and sufficiently trained in pharmacovigilance to fulfill the responsibilities outlined in the national pharmacovigilance guidelines. A database containing QPPV names, 24/7 contact details, and backup procedures was created to facilitate prompt follow-ups with the MAHs for any safety concerns.

Guideline development was challenging. There were few experts in pharmacovigilance. Furthermore, regulations supporting pharmacovigilance-related activities in the country were limited. The only way to overcome these shortcomings was training. Thus, the SFDA offered pharmacovigilance training for members of pharmacovigilance guidelines committee. In addition, available international pharmacovigilance guidelines were reviewed to select the most appropriate model for local implementation.

Selecting appropriate references for the new guidelines was another challenge. Adopting advanced regulations in a country where basic pharmacovigilance activities were lacking would not have made sense. Therefore, the committee members made massive effort to select the best model that pharmaceutical companies could implement and follow locally.

The committee chose to select the European Union's (EU) Volume 9 Pharmacovigilance Guidelines as an authorized reference for pharmacovigilance-related activities for many reasons. First, the European Medicines Agency (EMA) represents the world's largest union for drug regulatory authorities, and its regulations are

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