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REVIEW

Pharmacovigilance system in Saudi Arabia

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Abstract Pharmacovigilance plays an important role in ensuring that patients are receiving safe drugs. In Saudi Arabia, Saudi Food and Drug Authority, health institutions, marketing authorization holders and healthcare professional are involved in pharmacovigilance activities regardless of the level of the involvement. Although pharmacovigilance is well established in developed nations and it is considered a new concept in Saudi Arabia. It is a collective effort from various stakeholders to make pharmacovigilance successful toward promoting safe and effective use of medicines among the population. However, the practice of pharmacovigilance still needs more attention especially from marketing authorization holders and healthcare professionals. The aim of this review was to describe the current situation of pharmacovigilance in Saudi Arabia and the activities that have been conducted by the stakeholders.

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1. Introduction

Pharmacovigilance plays an important role in ensuring patients' drug safety. In the Kingdom of Saudi Arabia (KSA), it is considered a new concept and all stakeholders are still not fully functioning and applying all pharmacovigilance tasks. As this topic is considered new in Saudi Arabia and even in the region, pharmacovigilance has been strongly initiated by the Saudi Food and Drug Authority (SFDA) as there is a large department performing pharmacovigilance activities. There has been an increase in the number of reports over a short period of time. Also, other pharmacovigilance activities, such as periodic safety update, reports review and risk management plans have been performed. Other stakeholders have also started to implement pharmacovigilance activities; however, there is a variation in the level of implementation.

This review describes the current situation of pharmacovigilance in the Kingdom of Saudi Arabia and the activities being conducted by these stakeholders.

2. The healthcare system in Saudi Arabia

The healthcare system in the kingdom is under the jurisdiction of the Ministry of Health. The Ministry of Health offers healthcare services to the public through its complex organizational structures comprising 244 hospitals, 2037 healthcare centers, referral hospitals, security forces healthcare institutes with medical services, and so on. Saudi Arabia also boasts its own Red Crescent Authority, which undertakes an important and efficacious role in providing emergency services at the pre-hospitalization stage, either at accident sites or while transporting patients to the hospitals. In addition, this body serves a unique task of handling pilgrims during Hajj and Umrah at the holy places of Mecca and Medina.

Healthcare services in the kingdom are a highly sensitive area of development that needs continuous improvements. Hence, the Saudi Government deems healthcare services a priority, as is evident from the WHO ranking of the Saudi healthcare system at 26 among 190 countries all over the world (Almalki et al., 2011). Despite the untiring efforts of the government, there are still several components that require to be addressed such as a shortage of qualified healthcare professionals, changing patterns of disease, a poor health information system, the under-utilization of electronic health strategies, low Adverse Drug Reactions (ADRs) reporting and so forth (Almalki et al., 2011; Khan et al., 2012). ADR reporting through pharmacovigilance is gaining more attention in recent times. The consequences of ADRs are detrimental; however, they can be prevented if detected on time. Thus, the important aspect is their detection and minimization requiring a collective effort from all healthcare professionals including physicians, pharmacists, and nurses. In recent days, the professional role of pharmacists is gaining more recognition in the healthcare system as they are more involved in patient care (Chisholm-Burns et al., 2010; Kaboli et al., 2006). Thus, the concerned authorities desire a greater contribution from pharmacists to report ADRs, improve patient's health, and improve their economic outcomes (Hume et al., 2012; Sweis and Wong, 2000; van Grootheest et al., 2004).

3. Stakeholders in pharmacovigilance

The use of medicines is vastly increasing due to growing populations, the emergence of various health complications and an increased health consciousness among the people globally. Thus, it is important to assure the safe and effective use of medicines. This demands collective and ongoing efforts from different stakeholders such as pharmaceutical manufacturers, Government drug regulatory authorities (e.g. SFDA), healthcare professionals (e.g. physicians, pharmacists, nurses, paramedical staff, and so on), patients or patient parties, contract research organizations, hospitals, and clinics where clinical trials are conducted (Davies, 2015).

3.1. Saudi Food and Drug Authority (SFDA)

The Government of Saudi Arabia established the Saudi Food and Drug Authority in 2003. The prime objective of this regulatory authority was to regulate safe and effective use of medicines, medical devices, food items and even cosmetics in the kingdom (Saudi Food and Drug Authority, 2013a).

The SFDA consists of three main sectors: food, drug, and medical devices. Each sector has its own distinct role based on its nature of work (Saudi Food and Drug Authority, 2013b). As this paper is about the safety issues of medicines, we would like to focus on the role of the drug sector of the SFDA. Medicines have become an integral part of our lives for treating simple to complex health complications. However, lack of proper use of medicines and monitoring the consequences due to them are vital issues. Thus, SFDA realized the necessity to establish a separate unit, called the National Pharmacovigilance Center (NPC) to monitor the safety issues of medicines (Saudi Food and Drug Authority, 2013c). NPC