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
plays an important role in the detection of ADRs, their assessment and prevention, and this unit will ultimately expand to be a large executive directorate concerning pharmacovigilance and crisis management (Saudi Food and Drug Authority, 2013c). Originally, the word ‘pharmacovigilance’ is derived from the Greek word ‘pharmacon,’ which means ‘drug,’ and

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| A. Patient Details |
|--------------------|
| **Patient name or initial (Optional):** |
| **Date of birth:** |
| **Height:** |
| **Weight:** |
| **Health Institution:** |
| **Medical Record No:** |
| **Age:** |
| **Sex:** M | F |

| B. Suspected Drug(s) / Vaccine(s) / Herbal(s) /Cosmetic(s) and all other drugs used |
|-----------------------------------------------|
| **Drug name “Generic & Brand”** | **Manufacturer and batch No.** | **Dose / Route / Frequency** | **Start date** | **End date** | **Purpose of use** |
| 1 | | |
| 2 | | |
| 3 | | |
| 1 | | |
| 2 | | |
| 3 | | |

| C. Adverse Drug Reaction |
|--------------------------|
| **Adverse event including relevant tests/lab data and dates** | **Other relevant history, including preexisting medical conditions (diabetes, allergies, pregnancy, hepatic, renal etc)** |

| Date of event started: | Date of event disappeared, if applicable: |

| D. Action Taken |
|-----------------|
| **Drug withdrawn.** | **Dose reduced.** | **Dose increased.** | **Dose not changed.** | **Unknown.** | **Not applicable.** |

| E. Outcome of ADR (Tick all applicable) |
|-----------------------------------------|
| The patient **Recovered, date:** | **Recovering** | **No improvement** | **Fatal** | **Unknown** |
| Event subsided after stopping (dechallenge) | **No** | **Yes** | **Unknown** |
| Event reappear after reintroducing (rechallenge) | **No** | **Yes** | **Not applicable** |
| Specific antagonist or treatment used: | **No** | **Yes, specify:** |

| F. Seriousness of ADR (Tick all applicable) |
|---------------------------------------------|
| **Patient died, date:** | **Life threatening** | **Permanent disability** |
| **Hospitalization** | **Prolonged hospitalization more than 24 hr.** | **Congenital anomaly** |
| **Required intervention to prevent permanent impairment/ damage** | **Required Emergency Room (ER) visit** |
| **Cancer** | **Others...............................** |

| G. Reporter Details |
|---------------------|
| **Reporter name:** | **Profession (Specialty):** |
| **Address:** | **E-mail:** |
| **Phone / Mobile:** | **Fax :** | **Date:** | **Signature:** |

**Figure 1** Saudi Food and Drug Authority ADR-1 paper reporting form for healthcare professionals.
‘vigilare’ (Latin), which means ‘to keep awake or alert, to keep watch’ (Center, 2009; Soni and Kesari, 2014). WHO defines pharmacovigilance as ‘the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem’ (World Health Organization, 2014a). The concern of pharmacovigilance is not limited to allopathic medicines but also covers herbal, traditional, and complementary medicines; blood products; vaccines; and medical tools and devices (World Health Organization, 2014b). Pharmacovigilance not only reduce the ADRs but also shortens the duration of stays in hospital, lessens economic burdens, and reduces mortality (World Health Organization, 2014c).

Despite the NPC’s efforts to make available the reporting of ADRs online as well as on paper (Figs. 1 and 2 as examples), the under-reporting of ADRs by the public and HCPs is still prevalent. Thus, it requires collective and continued efforts to encourage ADR reporting. The online reporting form is available through this Web site, https://ade.sfda.gov.sa/ (Saudi Food and Drug Authority, 2013d).

3.1.1. Structure and duties of the Vigilance and Crisis Management (VICM) Executive Directorate

The SFDA realized the need for further strengthening pharmacovigilance. Therefore, it was decided to make an executive directorate, i.e. the Vigilance and Crisis Management (VICM) Executive Directorate with a more specialized function.

The VICM functions to follow up both marketed drugs and the ongoing assessment of the safety and quality of pharmaceuticals, side effects, and medication errors. The directorate also acts to prevent the risk of occurrence of a crisis of pharmacetical products and manage this, when possible, by taking appropriate standard actions in cooperation with other departments in the pharmaceutical sector.

The VICM is divided into the National Pharmacovigilance and Drug Safety Center (NPC), medication errors, and crisis management. Based on personal communication with SFDA, the VICM has been modified to include the benefit part of its tasks; therefore, the name will no longer be VICM. However, this information was not updated on the Web site or other authentic source of information (Saudi Food and Drug Authority, 2013c).

3.1.2. WHO Monitoring Center (Uppsala Monitoring Center) and the NPC

Participating in the UMC entails several obligations for the SFDA and also various advantages for the SFDA, such as performing signal detection using the VigiBase® system, which includes around 12 million reports (Vigibase, 2016). This helps to study any alarming signals that occur in Saudi Arabia. Also, there are other advantages such as an annual gathering to discuss methods to improve pharmacovigilance activities within the participating countries.
3.1.3. SFDA post-marketing activities

The strategic plan of SFDA is to set up the NPC. It sees the crucial importance of constructing a robust infrastructure for the NPC, in the form of strengthening the lines of staff and ensuring that the staff are qualified for the job; they are expected to have the necessary and relevant qualifications in addition to expertise. The NPC has prepared well-formulated reporting forms and a reliable database. These forms include forms for healthcare professionals and patients to submit any ADR. In addition, there are report forms for drug quality defects (Saudi Food and Drug Authority, 2013d; Wilbur, 2013). The establishment of an advisory committee is also vital, where it can advise the NPC on any growing issues or draw its attention towards ADR reports and similar cases (Saeed, 2014). More importantly, the NPC is expected to serve as the intermediary between hospitals and the reporting system, so that all issues that arise among hospitals can be addressed and steps for prevention can be laid out. However, before this can happen, the NPC helps all hospitals to be able to submit ADR reports.

In a broad sense, the most important task is to make people aware about ADRs, pharmacovigilance and people’s contribution. Therefore, VICM has facilitated the reporting of ADRs through various ways such as verbal, online or paper, telephone, fax, and email (Saudi Food and Drug Authority, 2013d).

The SFDA also promotes ADR reporting in the KSA so that regulatory action can be taken based on the ADRs received. It also provides information to physicians, pharmacists, and other healthcare professionals on ADRs. Regarding report statistics, 76,949 reports were received in 2014. Of the 76,949 reports received, 75,486 reports (98.1%) were ADRs, 697 (0.9%) were medication errors, and the remaining 770 (1%) were reports of poor quality. However, reports from Marketing Authorization Holders (MAHs) show an increasing trend. 73,067 reports (95%) were received from drug companies, 2856 reports (3.71%) were received from hospitals and only 131 (0.17%) reports were received from the general public (Saeed, 2014).

3.1.4. Periodic Safety Update Reporting (PSUR) and pharmacovigilance actions

The periodic safety update reporting (PSUR) was started in the early 1990s by the Council for International Organizations of Medical Sciences (CIOMS) and was widely accepted and implemented in many parts of the world including the Kingdom of Saudi Arabia (Klepper, 2004). A PSUR is a report that provides an evaluation of the benefit-risk balance of a medicine, which is submitted by MAHs to the SFDA in the ICH E2C(R2) Format (Klepper, 2004; Saeed, 2014). PSURs are considered as a valuable resource for pharmacovigilance data for any regulatory agency. The SFDA has received 817 PSURs; of them, 277 were reviewed, and 71 actions were taken for safety reasons. Those actions ranged from labeling updates to submission of risk management plans (RMP) (Saeed, 2014).

3.1.5. Electronic systems

At the planning stage of establishing the pharmacovigilance center, setting up an electronic system was one of the major tasks of the SFDA. Healthcare professionals established an electronic reporting form for their use. However, there were complaints that the form was too long. Therefore, a new electronic version of a four steps – similar to the United States FDA electronic reporting form – is used, which is easier to complete (Saudi Food and Drug Authority, 2013d). An advanced electronic database, Empirica Trace®, is used to collect, store, analyze, and evaluate the reports that come from pharmaceutical companies, healthcare professionals, patients, and other reporters. Vigibase® is another database that is used by the pharmacovigilance center at the SFDA (Saeed, 2014). It belongs to the World Health Organization-Uppsala Monitoring Center (WHO-UMC). It has around 12 million reports and it helps to perform data mining by the staff of Pharmacovigilance center to help them in the evaluation process (Vigibase, 2016). The SFDA is to continue using and evaluating electronic systems that can help in their daily processes and tasks.

3.1.6. Pharmacovigilance guidelines

The NPC has to carry out the significant task of implementing the pharmacovigilance guidelines and subsequently ensuring that the guidelines are adhered to. The Saudi pharmacovigilance guidelines have been adopted from the ICH volume 9a guideline, which is also used by the European Medicine Agency (EMA) (Saudi Food and Drug Authority, 2013e; Wilbur, 2013). However, the EMA has established a new guideline that is the Good Pharmacovigilance Practice Guideline (Xie and Tian, 2013). As a first step, after introducing the new European guideline, the VICM established a committee to review, adopt, and apply it in the KSA. The current guideline covered all required aspects to apply all pharmacovigilance activities by regulatory bodies, pharmaceutical companies, electronic systems, and some information for healthcare professionals. Furthermore, the health department at the Council of the Arab League has decided to have one document on Good Pharmacovigilance Practice for Arab Countries, which is also adopted from the EMA guideline with some modifications. However, the idea of having one guideline for Arab countries is not the same as the EMA guideline, as the Arab guideline is not applicable to all countries and each country could have its own guideline (Saad, 2014). Furthermore, the SFDA has recently published its own Pharmacovigilance guidelines, “Guidelines on Good Pharmacovigilance Practices,” implemented on September 1, 2015 (Saudi Food and Drug Authority, 2013f).

3.2. Marketing Authorization Holders (MAHs)

Still within the scope of pharmacovigilance, (MAHs) ensure the efficient organization of the system of pharmacovigilance and risk management to ensure that their products are liable and accountable in the market, and to ensure that appropriate action can be taken in the market when necessary. Another important point is to note that MAHs ensure that all information pertinent to the risk-benefit balance of a medicinal product is reported to the SFDA fully and immediately according to the legislation that has been formed (Saudi Food and Drug Authority, 2013f).

In terms of the roles and responsibilities that MAHs have to bear, one important aspect is to develop a system where they can gather, collate, and assess pharmacovigilance data. They
have to go through a legal channel to enable them to report any suspected adverse reactions. They also have to ensure that they meet the legal obligations with regard to the preparation and submission of periodic safety update reports. MAHs must respond whether there are any requests from the SFDA on additional information that is necessary to evaluate the risks and benefits of any medicinal product. Their job description also includes ensuring that the authorization of marketing is maintained and reflects the most updated information about the products. MAHs should also assign a person who is qualified to make sure that all these responsibilities are fulfilled (Saudi Food and Drug Authority, 2013f).

In simple terms, MAHs should be held accountable for overall pharmacovigilance for all medicinal products for which the company holds marketing authorizations within Saudi Arabia. Therefore, most of the MAHs in Saudi Arabia have started to have a pharmacovigilance department within their organizational structures. The task of this department is to make sure that all medications for each MAHs are followed and to monitor the safety of these medications. Several tasks are conducted by the qualified person of pharmacovigilance (QPPV) – the person who is responsible for conducting these activities – including reporting ADRs, preparing and submitting PSURs and/or risk management plans (RMPs), following up with any requirements from the SFDA or healthcare professionals (HCPs) with respect to the safety of their medications, conducting training for HCPs about pharmacovigilance, and post-marketing safety.

### 3.3. Health institutions and healthcare professionals

Pharmacovigilance has not been well practiced by hospitals/clinics in Saudi Arabia. This is due to lack of knowledge and awareness about pharmacovigilance among the HCPs, and the lack of follow-ups about ADRs. In addition, the Ministry of Health (MOH) should encourage and apply pharmacovigilance activities in its hospitals and clinics. However, some hospitals within the MOH and other sectors have started implementing the pharmacovigilance concept. Some of these hospitals have established a medication safety officer (MSO) who has a job description similar to the QPPV in pharmaceutical companies (Aljadhey et al., 2014). The MSO is responsible to ensure the safety of medications inside the hospital by applying all policies and procedures that are set up by the hospital itself or by the SFDA. The MSO also has an important role in training and educating all HCPs in their health institutions, as safety of medications is the prime responsibility of all HCPs. In the hospitals that have this department, the MSO is located either within the pharmaceutical care department or within the quality department within the hospital. Regardless of their location, they apply the same tasks.

HCPs are not well trained or educated in pharmacovigilance and the safety of medications and this could be the reason that these concepts are not taught in most health colleges (i.e., medicine, pharmacy, nursing, etc.) and that there are not many training courses on pharmacovigilance in Saudi Arabia (Aljadhey et al., 2014; Alrwisan et al., 2014; Khan et al., 2012; Mahmoud et al., 2014). Therefore, there is a need for considerable efforts to train and educate all HCPs in Saudi Arabia in pharmacovigilance and medication safety.

### 3.4. Patients

Patients or even healthy individuals are not currently involved in the pharmacovigilance or medication safety activities. There are several reasons for this: first, the HCPs themselves are not promoting and trained in pharmacovigilance; second, pharmaceutical companies do not perform any educational activities for the wider society with respect to pharmacovigilance and medication safety; third, there is a lack of patient counseling in both government and private health institutions. However, this is a global concern and all stakeholders have to play their role in raising patient awareness on this issue (Jha et al., 2014).

### 4. Expert opinion

The pharmacovigilance system in Saudi Arabia is based on the European system and most of the activities conducted were taken from the European guidelines and practices. SFDA provided the required resources to perform the needed pharmacovigilance activities. Thus, the pharmacovigilance department performed most of the services; however, there remain activities still not conducted by the SFDA, such as conducting post marketing safety studies inside Saudi Arabia and a complete risk management system.

In the future, there is a need for all stakeholders including the SFDA, pharmaceutical companies, and HCPs to improve their performance with respect to pharmacovigilance activities. Pharmaceutical companies have to understand that there is a need for pharmacovigilance to be implemented in a well-resourced department to perform the full pharmacovigilance activities. Also, they should apply the activities based on the SFDA guidelines. Furthermore, HCPs have to realize their responsibilities, as they are the means to detecting ADRs with their patients.

### 5. Conclusions

Pharmacovigilance is considered a new concept in Saudi Arabia. However, there are good initiatives being conducted by some stakeholders, including the SFDA and some pharmaceutical companies and hospitals. Nevertheless, there is a need to enhance the quality of work that has been done to date by these stakeholders and there is a need for MAHs and HCPs to play their role with respect to pharmacovigilance and medication safety. Also, some further actions are suggested such as having a gateway to facilitate the transmission of ADR reports and to increase the number and quality of partnership relations between all stakeholders.

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