Chapter 4
Challenges Facing Adverse Drug Reactions Reporting and Counterfeit Drugs Monitoring

ABSTRACT

This chapter investigates in a case study the limitations of adverse drug reactions reporting (ADRr) and the challenges facing counterfeit drugs monitoring in the African developing countries with a focus on the Republic of Benin and proposes solutions to improve the adverse drug reporting method and infrastructures as well as the counterfeit drugs monitoring. The study aims at implementing an ADRr system using the m-health technology to overcome the limitations and ease the use of the "yellow card" in the developing world. Furthermore, a real-time notification system is provided to promptly disseminate among the populations any registered and proved ADR.

INTRODUCTION

Pharmacovigilance History

WHO defines Pharmacovigilance (PV) as the science and activities relating to the detection, evaluation, understanding, and prevention of drug adverse reactions or other drug-related problem (WHO, n.d.). The pharmacovigilance is consisted of recording and evaluating side or adverse effects resulting from the use of drugs. Its roles are to (i) report adverse drugs reactions by healthcare

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professionals, companies dealing with drugs, and collect information by the public pharmacovigilance organization, (ii) register, evaluate, and use the collected information, (iii) monitor drug safety.

Although, it is reported in the Hippocrates: "*primum non nocere*" that in the ancient time, the doctors who prescribed a medicine (opium, strychnine ...), also monitored the individual tolerance. The pharmacovigilance is, however, a recent science, unlike the medicine. The pharmacovigilance began in the USA in later 1938 after President Franklin Roosevelt signing the ''Federal Food, Drug and Cosmetics Act''. This law foresees the necessity and the obligation for pharmaceutical companies to report to the FDA concerning the safety of all medicinal drugs. (Caron, Rochoy, Gaboriau, & Gautier, 2016). European countries like France start their pharmacovigilance in earlier 1950. The pharmacovigilance was subsequently widely implemented in all high-income countries and only recently developing countries (Sommet, Bagheri, & Montastruc, 2007).

The main event leading to the adoption and implementation of the pharmacovigilance as known nowadays are among others:

1. In 1937 the sulphanilamide elixir causing 105 deaths as a result of poisoning due to a lack of formulation enabled the improvement of pharmaceutical regulation. (Akst, 2013; FDA, n.d.)
2. In 1961 thalidomide causing phocomelia in infants whose mothers took the drug. This event allowed WHO to create an international drug surveillance program (the birth of the first national pharmacovigilance systems).
3. In 1969, subacute retrobulbar optic neuritis with clioquinol in Asia revealed an ethnic susceptibility to drugs and their adverse effects.

The Program for International Drug Monitoring (PIDM), which, in 1960, was consisted of ten (10) developed countries and expanded over the years, was launched in 1992 in Africa. Morocco and South Africa have joined the PIDM as the first two African countries. In 2006 the majority of African countries joined the PIDM. In 2015, 35 of 54 African countries are already members of the PIDM (Ampadu et al., 2016). Among the African countries joined the PIDM, 24 countries have the status of full members and 9 are associate members in 2010. The Republic of Benin is till 2010 an associate member(Isah, Pal, Olsson, Dodoo, & Bencheikh, 2012) and becomes a full member from 2011 PIDM (Ampadu et al., 2016).

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