The Pharmacovigilance System in Ghana

The Food and Drugs Authority (FDA) is the National Pharmacovigilance Centre and coordinates Pharmacovigilance activities in Ghana.

Ghana joined the WHO International Drug Monitoring Programme in November 2001 as the 65th member of the programme and the first country in West Africa.[1]

The FDA serves as a repository for reported adverse reaction reports and currently, the major source of spontaneous reports is from healthcare professionals and marketing authorization holders (MAHs).

To promote ADR and AEFI reporting, the FDA has a decentralized Pharmacovilance (PV) where safety reports received from healthcare professionals in the regions comes through the nine Regional Offices with designated Officers, Regional PV Officers. There are also Institutional Contact Persons (ICPs) in almost all healthcare facilities which serve as the link between the FDA and other healthcare staff in the institutions. The FDA also collaborates with the Public Health Programmes (PHPs) to ensure the safety of medicines used in these programmes are safe, efficacious and of good quality.

As with most spontaneous Pharmacovigilance systems, the PV system in Ghana is still plagued with underreporting. In 2015, the FDA received a total of 697 spontaneous reports, with the population of Ghana being 27.41 million[2]. This therefore made the number of spontaneous reports received per 1,000,000 population in that year to be 12.7% of the WHO-UMC recommendation of 200 reports per 1,000,000 population per year.[3] However, with the reports received, a number of timely safety related regulatory decisions have been taken including the withdrawal of substandard and unregistered medicines from the Ghanaian market, dear healthcare professional letters and alerts aimed at protecting public health and safety.

The FDA has an online database, SafetyWatch System (SWS) that is ICH E2B compliant for management of reports received. Spontaneous reports received are sent to the WHO International Drug Monitoring Programme as an E2B (xml) file.

The major strategy for promoting spontaneous reporting in Ghana is through awareness creation and training programmes for healthcare professionals. The FDA has also since 2015 launched a number of initiatives to improve the adverse reaction reporting rate and improve on signal generation. These are the Qualified Person for Pharmacovigilance (QPPV) ensuring mandatory industry reporting and Patient

[1] Uppsala Monitoring Centre (UMC). http://www.who-umc.org/DynPage.aspx?id=100653&mn1=7347&mn2=7252&mn3=7322&mn4=7442. Assessed September 5, 2016
[2] World Bank (WB). http://www.worldbank.org/en/country/ghana. Assessed September 5, 2016
[3] Uppsala Monitoring Centre (UMC) . http://www.who-umc.org/DynPage.aspx?id=108476&mn1=7347&mn2=7252&mn3=7322&mn4=7558. Assessed September 5, 2016

Reporting Programmes[4,5] and Patient Safety Centre, an initiative undertaken in collaboration with community pharmacies. There is also a programme in collaboration with the Ghana Health Service to peer review pharmacovigilance performance of health facilities using the Pharmacovigilance Assessment Tool (PAT) adapted from the Indicator-Based Pharmacovigilance Assessment Tool (IPAT) developed by Strengthening Pharmaceutical Systems (SPS) programme.[6] This is to ensure that pharmacovigilance issues are promoted within the healthcare facilities by measuring their PV performance using a set of indicators.

The National PV Centre has also successfully collaborated with the Nursing and Midwifery Council of Ghana (NMCGH) to incorporate PV into the curriculum for training nurses and midwives in training institutions in Ghana. The PV Centre also makes presentations to students in the Pharmacy training schools in Ghana and is working with these institutions to make PV an integral part of the training curriculum.

The FDA collaborates with and is mentored by other international organizations such as the World Health Organization (WHO), UK Medicines and Healthcare Products Regulatory Agency (MHRA), and the Netherlands Pharmacovigilance Centre (LAREB).

[4] Uppsala Monitoring Centre (UMC). http://www.who-umc.org/graphics/29603.pdf. Assessed September 5, 2016
[5] Ghana News Agency (GHA). http://www.ghananewsagency.org/health/fda-launches-patients-safety-programme-104704. Assessed September 5, 2016
[6] Strengthening Pharmaceutical Systems (SPS) Program: Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries. http://pdf.usaid.gov/pdf_docs/PNADS167.pdf. Assessed September 5, 2016