First Batch of Qualified Person for Pharmacovigilance (QPPV) Completed Training

The Ghana Food and Drugs Authority (FDA) in collaboration with the World Health Organization Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana, Accra, Ghana (WHO-CC) has completed the training for the first batch of Qualified Persons for Pharmacovigilance (QPPVs) held from 20th May 2015 to 5th June 2015; this training is the first ever be carried out in Africa.

The training programme is line with the new requirements in Part 7, Section 125 of the Public Health Act, 2012, Act 851 and the Food and Drugs Authority (FDA) Guidelines for Selection of Qualified Persons for Pharmacovigilance which makes it mandatory for Marketing Authorization Holders (MAHs) of pharmaceutical products to have a qualified person responsible for pharmacovigilance resident in Ghana to oversee the safety monitoring of products marketed in the country. The requirement further states that the QPPV should receive a formal training in pharmacovigilance recognized by the FDA, and since this training is at the moment not being offered by any providers around the globe, the FDA partnered with the WHO-CC who together with the FDA have recently been designated as Regional Centre of Regulatory Excellence in Pharmacovigilance by the Africa Union to run the course.

The course has a minimum of 60 hours contact time and was developed to meet the busy schedules of the senior pharmaceutical company executives who participated in the course.
The course has 9 modules includes the following:

1. Introduction to pharmacovigilance;
2. The QPPV: Legal framework, Roles and Responsibilities;
3. Pharmacovigilance Quality System;
4. Individual Case Safety Reports, Data Management, Coding and Case Causality Assessment;
5. Pharmacovigilance Methods;
6. Periodic Safety Update Reports (ICH E2C) and Periodic Benefic Risk Evaluation Reports (ICH E2 R1);
7. Signals and Signal Management;
8. Pharmacovigilance Audits and Inspections;
9. Communication and Crises Management in Pharmacovigilance.

Participants for the first phase of the QPPV training represented multinational companies such as Astra-Zeneca, Bayer, Roche, Pfizer, MSD, Novartis, Novo Nordisk, Eli Lilly, Servier, Janssen, Sanofi, Merck and GlaxoSmithKline.

Figure 1

The second phase of trainings is scheduled for the third quarter of 2015 on a date to be communicated to prospective participants and is open to importers and local manufactures of pharmaceutical products.

Regulators and pharmaceutical company representatives from other African countries are invited to participate in this course.

Importers of pharmaceutical products and local pharmaceutical companies are encouraged to participate in the training because this is part of the new legal requirement and will form the basis for renewal of marketing authorizations and registration of new products.

The FDA believes active involvement of the pharmaceutical companies in the safety monitoring of marketed products will led to improvement in reporting rate of adverse events which stands at an average of 12 reports per 1 million population per year and enhance the chances of signal detection leading to greater patient protection to improve public health and safety.