NOTIFICATION OF IMPLEMENTATION OF THE SAFETY MONITORING REQUIREMENTS IN THE PUBLIC HEALTH ACT 2012, ACT 851

The Food and Drugs Authority (FDA) will from **30th June, 2017** commence implementation of the safety monitoring requirements in accordance with Section 125 of the Public Health Act 2012, Act 851. This follows four (4) successful training programmes organized by the World Health Collaboration Centre for Advocacy and Training in Pharmacovigilance (WHO-CC) in collaboration with the FDA.
The training programmes have offered assistance to Marketing Authorization Holders (MAHs) to put in place systems, structures and the personnel to monitor the safety of all marketed products to ensure patients safety. Following the training programmes pilot inspections have been conducted to further assist MAHs to develop appropriate pharmacovigilance systems to further ensure safety of marketed products.

The implementation of the requirements involves Good Pharmacovigilance Practice (GVP) inspection and the exact date for the inspection will be communicated individually to all Marketing Authorization Holders (MAHs) in due course.

The inspection will be conducted as per the underlisted Food and Drugs Authority guidelines which are available on the FDA website at http://www.fdaghana.gov.gh/.

1. Food and Drugs Authority's Guidelines for Conducting Pharmacovigilance Inspections.

2. Food and Drugs Authority's Guidelines for Qualified Person for Pharmacovigilance.

3. Food and Drugs Authority's Guidelines for Reporting Adverse Reactions.

4. Food and Drugs Authority's Guidelines for Safety Monitoring of Medicinal Products.

Cooperation of all MAHs and Local Representatives is required to enable the FDA carry out this important activity in fulfillment of Public Health Act 2012, Act 851 to ensure public health and safety.