FDA HOLDS STAKEHOLDER MEETING ON THE REGULATION OF MEDICAL DEVICES

As part of its mandate to regulate Medical Products with the aim of protecting public health, the Food and Drugs Authority (FDA) held a stakeholder meeting on the regulation of medical devices on 10th August 2017.

The objective of the programme was to equip participants with the knowledge on the Guidelines and framework for the regulation of medical devices. It also explained the importance of Regulation with regard to safety, quality and good performance of medical devices.

Opening the meeting, the Acting Chief Executive Officer, Mrs. Delese Darko said the importance of current levels of regulation with regard to safety, quality and good performance of medical devices cannot be over emphasized. She also stated that globally, medical devices are indispensible in health care delivery systems, from prevention through diagnosis, mitigation to treatment.

The stakeholders were taken through different presentations including the Law that governs regulations of medical devices, registration and approval processes, registration guidelines, and classification of medical devices in Ghana.

The Stakeholders were further informed of the various testing units in the FDA Laboratory, the Laboratory's current accreditation to ISO and IEC standards, protocols of the Laboratory as well as clients the Laboratory serves.

Another critical area of importance that the stakeholders were taken through were the required permits for importing medical devices, issuance of permits, charges on consignments, permit vetting processes, physical inspection processes, documentation required and clearance procedures.

The Representative from the National Regulatory Authority (NRA), Dr. Henry Lorlorvi, spoke about the regulation of radiation emitting devices, functions of the NRA, system of authorization of radiation emitting devices, regulatory inspections and frequency, regulatory enforcement and emergency preparedness.

Closing the meeting, the Ag DCE for Monitoring and Evaluation of the FDA thanked the participants for their presence and contribution. He also emphasized the importance of cooperation between the FDA and the stakeholders to ensure efficacy, safety and performance of medical devices.