FDA/CPE/SM/0002 16th June, 2017

SUMMARY OF STAKEHOLDERS MEETING ON REVIEW OF DOCUMENTATION REQUIREMENTS FOR REGISTRATION OF HERBAL MEDICINAL PRODUCTS ON 13TH JUNE, 2017

The FDA has organized a stakeholders' meeting to review the current requirements for the regulation of herbal medicines in Ghana with the aim of improving the overall quality, efficacy and safety of products on the market.

In the regulation of Herbal medicines, the FDA grouped medicines into two main categories: those for acute disease conditions and those for chronic disease conditions depending on the condition and duration of the treatment regime.

Medicines for conditions such as Candidiasis, Gonorrhoea, Sexual weakness and Typhoid fever were put under the category of chronic diseases. For such products, a clinical trial report based on the FDA guidelines for allopathic medicines was required.

It has become necessary to review and explore the possibility of using other proven laboratory models rather than complete human clinical trials to access the efficacy of these products since the request for human clinical trials was difficult for the industry to meet.

Instead of Clinical Trial, testing could be done using appropriate and internationally recognized laboratory models to ascertain the efficacy of products for conditions such as Typhoid, Candidiasis, Gonorrhoea and Sexual weakness.

Such methods include the following:

- Zones of inhibition test for antimicrobial and antifungal activities – a measure of Equivalence will be expected with a major brand leader.
- For Antiviral activities – culture on living tissues or cells.
- Animal Pharmacology Models for sexual and erectile dysfunction testing, models for Antipyretics etc.

The Authority requested for the help of the Recognized research institutions to acquire the capacity to assist industry provide this documentation for Registration as well as to assist industry acquire their own capacity to develop testing models for research and development (R&D) of new products.