EFFECTIVE USE OF PHARMACOPOEIAS

Presented by:
Samuel Asante-Boateng
Director, Drugs and Herbal Medicines Registration, FDA Ghana.

What is a pharmacopoeia

- An official collection of approved pharmaceutical standards.
- It comprises standards/requirements on the quality of medicinal products and of the substances used to manufacture them.
- These standards help ensure the quality and safety of essential medicines by providing analytical methods and appropriate limits for testing and assessing the APIs, excipients and FPPs.
- It is an important pillar of drug safety
- It also gives the type of packaging material to be used for the medicinal product to protect its integrity

PHARMACOPOEIAS IN USE

- There are different types of pharmacopoeias (USP, EP, BP, JP, IP etc)
- They all share the common goal of publishing and producing quality standards for pharmaceuticals to ensure public health and safety.
- Depending on the country, one or several pharmacopoeia(s) may be used;
- In Ghana, there is a legislation for the use of the following;

PHARMACOPOEIAS IN USE-Cont'd

- The British Pharmacopoeia (BP)
- The Extra Pharmacopoeia
- The United States Pharmacopoeia
- The International Pharmacopoeia
- The standards, codes of practice, guidelines and recommendations issued by the Codex Alimentarius Commission, and
- Any other work of reference adopted and approved by the Authority

ROLE OF MODERN PHARMACOPOIEA

- Furnish with quality specifications for APIs, FPPs and other general requirements
- The existence of such specifications and requirements is necessary for the proper functioning or regulatory control of medicines manufacture.

PHARMACOPOEIAL USE

- General Notices;

  - Forms the foundation of pharmacopoeia requirements and define the terms used in monographs

- General monographs

  - Requirements for the particular dosage form and that for pharmaceutical preparations

- Specific monographs

  - providing mandatory standards for the product

- Monographs for bulk drug substances and other ingredients

- IR reference spectra
- Appendices