➢ General Administration for Registration of Herbal Medicines

Q1: What is the Herbal Medicine?

Any finished, labeled medicinal product (for oral, rectal, external or inhalation uses), exclusively containing active substances which can be:

- one or more herbal substances or,
- one or more herbal preparations or,
- one or more herbal substances in combination with one or more herbal preparations.

Herbal medicines may contain conventional excipients in addition to the plant-based active ingredients.

Q2: May herbal medicines contain ingredients which are not of plant origin?

In some cases, they may also contain, by tradition, natural organic or inorganic ingredients which are not of plant origin.

However, products to which chemically-defined active substances have been added, including for example, synthetic compounds and/or isolated constituents from herbal materials e.g. (Atropine, Diosgenin) are not considered to be herbal medicinal products.

Q3: May Herbal Products contain vitamins/minerals?

Herbal medicinal products may contain vitamins/minerals as supplementary substances.

The action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication.

Q4: What are the routes of administration allowed for 'Herbal Medicines'?

Oral, rectal, external or inhalation.

Q5: What are the objectives of the Egyptian guidelines for registration of Herbal Medicines?

The purpose of this document is to propose a framework for the registration of herbal medicines. The proposed framework is based on the criteria of pharmaceutical quality, safety of use and therapeutic efficacy; it should accelerate the registration of herbal medicines of consistent quality and encourage the development of herbal medicines from traditionally used Egyptian herbs and plants.

Q6: What are the specific purposes of Egyptian guidelines for registration of Herbal Medicines?

- To set a definition of herbal medicines.
- To propose a classification scheme for herbal medicines.
- To propose general minimum regulatory requirements for the registration of herbal medicines including minimum requirements to assess safety, efficacy and quality.

Q7: How to control quality of Herbal Medicines?

Quality control of herbal medicinal products is the shared responsibility of manufacturers and regulatory bodies. The base for quality control is the establishment of appropriate specifications to conform analysis and stability standards. Information can be found in official pharmacopoeias and monographs or other related references. Herbal medicines in Egypt, as other pharmaceutical products, are manufactured in factories according to Good Manufacturing Practices (GMP).

Q8: Which authority regulates the registration of Herbal Medicines in Egypt?

All local and imported herbal medicines should be registered by Egyptian Drug Authority (EDA) before marketing.

Q9: Types of marketing of Herbal Medicines?

Local and for export.

Q10: What are the purposes of the Egyptian herbal monograph?

- Provides scientific information on the safety, efficacy and quality of wild Medicinal plants.
- Facilitates their appropriate use.
- Facilitates information exchange and registration procedures.

Q11: What are the contents of the Egyptian herbal monograph?

Each monograph contains all the available information and scientific results on the selected species include the following: names, synonyms, parts used for medicinal purposes, major chemical constituents, medicinal uses (indications), herbal preparations correlated to the medicinal use, posology and method of administration correlated to medicinal use, contraindications, special warnings and precautions for use, interactions with other medicinal products, other forms of interaction, effects on fertility, pregnancy, lactation, ability to drive, using machines, undesirable effects, overdose, relevant biological activities and if any additional information.