Guideline

Central Administration of Pharmaceutical Products
General Administration of Herbal Products Registration

Executive Procedures of Reviewing the Cards of Herbal Medicine Products

Year 2021

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The inner and outer labels of all locally manufactured herbal medicine products, locally manufactured under a license from abroad, imported products as well as locally manufactured products for export only, shall be reviewed in accordance with the following rules.

Scope

The cards of herbal medicine products shall be revised at the General Administration of Herbal Products Registration affiliated to the Central Administration of Pharmaceutical Products at Egyptian Drug Authority (provided that the links designated for this purposes on the website shall be used).

List of Abbreviations

CPP: Certificate of Pharmaceutical Product.

Free sale: Free circulating and selling certificate.

Batch No: Batch number.

Mfg. Date: Manufacturing date.

Exp. Date: Expiration date.

EDA. Reg. No: Registration number in Egyptian Drug Authority.

Definitions

1. **Herbal medicine**: It is a finished pharmaceutical product that is taken orally, rectally, inhaled or by the external use. Its active ingredients contain one or more herbal substances one or more herbal composition or one or more herbal substances in combination with one or more of these herbal products. The herbal medicine may contain, in addition to its active ingredients of plant origin, traditional excipients. It may also contain in some products natural organic or inorganic ingredients of non-plant origin or some vitamins and minerals as complementary ingredients that have an auxiliary effect to the active herbal ingredients in accordance with the properties specified shown by the indications. Herbal teas used for medical purpose can be

accepted as a herbal medicine.
The products to which chemically defined substances are added to their active ingredients such as synthetic compounds or components separated from herbal materials such as (atropine and diosgenin) shall not be considered a herbal medicine.

2. **The company**: It is the company applying to register a product and it owns all the product legal rights.
3. **The Factory**: It is a manufacturer designated for producing of the pharmaceutical products, licensed in accordance with applicable laws and conforms to the good manufacturing requirements approved by Egyptian Drug Authority.
4. **Certificate of Registration and Circulation of Pharmaceutical Product (CPP) Certificate of Circulation and Free Sale**: It is a certificate that includes the product data to be exported. This certificate is issued by the competent authority in the exporting country and it is addressed to the importing country.
5. **Reference countries**: They are a group of countries specified by a decision issued by the Technical Committee for Drug Control.
6. **Scientific Committee**: It is the Specialized Scientific Committee for Herbal Medicines.

Applied Procedures

Data required to be written/labeled on the outer cover

Local product:

The following shall be written on the outer package:

- All the letters that make up the trade name shall be written in a clear, legible handwriting.
- All data shall be written in Arabic and English on the outer package and the company has the free will in evaluating the cards in the way that does not

conflict with the data clarity.

- The active ingredients that make up the product and their concentrations as approved shall be written in both Arabic and English.
  (In the case of the product contains more than 3 active ingredients, the company may submit a request to study the possibility of writing them on only one side of the package in English in the way that does not conflict with the data clarity).
- writing the pharmaceutical form as it is approved on both sides of the package below the trade name, in both Arabic and English.
- The number of units composing the package in case of solid products and the size in case of liquids, provided that they are approved.
- labeling the logo or trademark of the company owning the product in addition to submitting an undertaking from the company possessing this logo.
- Explaining the method of use, such as: topical, by inhalation or orally… etc
- Storage conditions: Storage conditions shall be written as they stated in the approved stability study.
- Precautions of using the product (such as shake before use...).
- The company is allowed to write the authorized indications of the product mentioned in the internal leaflet and write the phrase (please read the internal leaflet to know the indications, dosage and warnings).
- The phrase (Keep out of reach of children) shall be written on the outer package of all the pharmaceutical products.
  - Batch No.
  - Mfg. Date
  - Exp. Date
  - EDA. Reg. No.
  - The approved price of the product.

- The company is allowed to lay cartoon drawings related to the indications of the product. It is also permitted to lay a picture of real people, provided that the company shall undertake to bear the full responsibility for the cartoon drawings and pictures of real people laid on the product labels against the third parties, without any responsibility on the part of the Egyptian Drug
  Authority against third parties. The company is allowed to lay a picture of a herb after ensuring that this herb is one of the product components.
- In the case of human medicines or dietary supplement converted into herbal medicines, the companies are allowed to retain the outer appearance of the package. The companies are also permitted to apply to change the outer appearance of the package in accordance with the applied rules.
- The name and address of the factory, name of the company owning the product in detail (telephone – e-mail), product barcode, if any and the name of any other party that participated in the phases of manufacturing of the product, as mentioned in the registration license.
- In case of the product has more than one concentration, the external appearance of the package of each concentration shall be clearly distinguished.
- Any other contents inside the package, such as (dropper, syringe, standard… etc.) shall be written, provided that they shall be approved.
  - All pharmaceutical form abbreviations, such as:
    - (MR-CR-SR-XL-ER) shall be translated in Arabic to (أقراص ممتدة المفعول).
    - (EC) shall be translated in Arabic to (أقراص مغلفة معوية أو ذات كسوة معوية).
    - Delayed-release products (DR): Are enteric-coated compositions that translated in Arabic to: كبسولات متأخرة الانطلاق (containing enteric-coated granules).

Imported herbal medicine products, they include the following:

Imported product [Bulk]:

All data must be written on the packaging, as is the case of the locally manufactured products.

Finished imported product (Finished):

- The package data shall be reviewed according to the data mentioned in the Certificate of Pharmaceutical Product (CPP) and matching to the approval of proceeding with the procedures. The storage conditions shall be reviewed in accordance with the Stability Committee decision in addition to submitting undertakings of writing the following data:
- Batch No., Mfg. date and Exp. date
- Importer's name, address and telephone number (in Arabic)
- EDA. Reg. No.

Data essentially required to be written on the inner cover

(Label) in the case of (bottles & jar). In this case the following data must be written:

- The product name.
- The product pharmaceutical form.
- The active ingredients that make up the product as it is approved
- Storage Conditions. The storage conditions shall be written as indicated in the approved stability study
- Precautions for using the product (such as shake before use... etc.)
- The phrase (Keep out of reach of children) shall be written on the outer package of all pharmaceutical products.
- The company is allowed to write the authorized indications of the product mentioned in the internal leaflet and write the phrase (please read the internal leaflet to know the indications, dosage and warnings).

- Mfg. Date.
- Exp. Date.
- EDA. Ref. No.
- Batch No.
- The factory name and the name of the company owning the product in detail (address, phone, fax and e-mail) and the product barcode.
- The logo or trademark of the company owning the product.

AL-FOIL in the case of (strips & blister). In this case the following information must be written:

- The product name, the pharmaceutical form, the company owning of the product or the abbreviation mentioned in the commercial registry if any, the logo, or
- The logo is sufficient if the company name is clearly visible.

How to Apply

- A cover letter shall be submitted on the stationary of the company stating the reason of approving of the package. It shall be accompanied by the product's registration documents.
- The application shall be uploaded to the Google drive of the Herbal Medicine Registration Department in the Names and Cards link:

https://forms.gle/yDcDWofGzAEaH1VA8

- After reviewing the application by the Names and Cards Section at the Herbal Medicines Registration Department, the company shall be notified of the required documents via the e-mail.
- After fulfilling the required documents by the company, an e-mail shall be sent from the company to schedule an appointment to submit the colored copies, including the required amendment.
- After reviewing and approving the package, it shall be delivered to the company by the competent administrator