Guideline

Central Administration of Pharmaceuticals Products
General Administration For of Herbal Products Registration

Executive Procedures of Reviewing the Names of Herbal Medicine Products

Year 2021

Code: EDREX:GL.CAPP.008

Version No.: (1)

Issue date: September 2021

Effective date: September 2021

Table of Contents

Introduction

The locally manufactured herbal medicine products, the locally manufactured under a license from abroad as well as locally manufactured products intended for export only shall subject to choosing a name by Egyptian Drug Authority in accordance with the following procedures.

Scope

Scrutinize the selection of trade names of herbal medicinal products in order to avoidance the similarity of the proposed name to the registered, under registration or submitted for registration names of medical products that have approval for the name (provided that using the links designated for that purposes on the electronic website).

List of Abbreviations

CPP: Certificate of Pharmaceutical Product

Toll: A local product manufactured by a third party

F-Toll: A local product manufactured by a third party

Under license: A local product manufactured under a permission from abroad

Definitions

1. **Herbal medicine**: It is a finished pharmaceutical product 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 extracted from a 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 herbal active ingredients in accordance with the properties specified 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

The herbal medicine products locally manufactured. It includes the following:

First- Local Product:

The proposed name shall not be similar to the names of other medical products presented in the database, registered or under registration, in terms of pronunciation or writing in Arabic or English.

1. When reviewing the name, in the case of mismatching the active ingredient (s), the different letters between the proposed name and the registered or under-registered trade names must be at least three letters, but in the case of the product

containing the same (active ingredient(s)) or that the products have the same indications, the difference may be limited to only two letters.

In case of the brand name differs in spelling and pronunciation, the number of different letters shall not be taken into account.

2. The scientific name of the active ingredient is permitted to be used (if it exists alone) by placing the full or the abbreviated name of the company registered in the commercial registry (in case of the abbreviated name is registered in the commercial registry) next to the active ingredients name.

3. The names that contain therapeutic properties or names of diseases shall be allowed, whether in Arabic or English, provided that they shall not conflict with the product indications.

4. The names that have a syllable indicating a special description shall not be approved, for example: (..., fast, live, slim, diet, health, safe, pedi, kiddi, elder, junior, old, young… etc.) in the event that there is a scientific evidence and it is consistent with the product indications.

5. The vowel letters (A, E, I, O, U) shall not be counted among the letters that differentiate between the names if they does not affect the pronunciation (i.e. in case of deleting this letter, the pronunciation does not change).

6. The following letter combinations shall be counted as one letter: ((Sh, Ch), (I, Y, E) – (S,C,O,U) – (C,K,CH) – (Q, K) – (B), P) - (D, T), (Z, X)) if they are similar in pronunciation.

7. For line extension, the same name shall be obtained after reviewing the previous name.

8. In cases of line extension, it is permissible to add the syllables (Extra Plus, Forte and Co… etc.) to the name in the way that correspond to the approved composition.

9. Any syllable that gives a meaning or suggestion does not match with the indications, composition or safety of the product submitted for registration, shall be prohibited, for example:

(Adeno) in a compound does not contain (Adenosine)

(Neuro) in a compound does not refer to (Neurology)

10. Any syllable in the name that suggests a pharmaceutical form that is inconsistent with the pharmaceutical form submitted for registration, shall be prohibited, example: tab, cap, gel… etc.

11. It is not permissible to use common names for non-pharmaceutical products, such as car brands, food, drinks... etc.

12. In the case of human pharmaceutical products or nutritional supplements converted into herbal medicines, the product trade name shall be retained in addition to take a new herbal medicine registration number and the company may apply to change the name in accordance with the applied rules.

13. The company is allowed to change the chosen name by submitting an application on the company's stationary explaining the reason for the change and paying the prescribed fees.

Second: Imported herbal pharmaceutical product, it contains (Bulk products) & (Finished imported product)

- For imported products, the name shall be reviewed based on the name written in the CPP. In case of the name conflict with the names of other registered or under-registration products, it shall be presented to the Technical Committee for Drug Control.
- For imported products, the name shall be reviewed in order to match the name circulated in the country of origin only. If another name is requested by the company, it must be circulated under the same name in another reference country.
- The company has the right to write or translate into Arabic any of the following marks (©, TM, R) on the trade name in case of the product obtained a certificate proving that the product name is registered as a trademark.

Third: Herbal medicine products manufactured locally for export only:

The name is chosen provided that it does not match to other registered names for other companies.

How to Apply

- After receiving the approval of the Specialized Scientific Committee for Herbal Medicines to proceed with the registration procedures within 3 months from the date of issuance of the approval, a letter shall be submitted on the company's stationary. The letter shall state the company's request to choose a trade name for the submitted product, approval of the Specialized Scientific Committee for Herbal Medicines and a list of names contain 20 suggested commercial names. The said letter shall be uploaded on Google drive for the Herbal Medicine Registration Department at the following link for Names and Cards:

https://forms.gle/yDcDWofGzAEaH1VA8

- The names shall be examined in the order in which they were presented by the company on the list. Such list shall be reviewed by the competent pharmacist.
- In case of approval, a letter shall be issued to the company indicating the new name.
- In the event of rejection, the company shall be notified via the e-mail. In such case the company must submit a new list of names.

The marketing officer and the registration representative are preferred to cooperate in establishing the list of names to reduce medical errors and facilitate advertising for the company.