Notice to applicant

Central Administration of Pharmaceutical Products
General Administration for Herbal Medicine Registration

Mechanisms for Herbal Medicines Products Registration under the Fast Registration System

(Fast track)

(2020)

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First: For the imported products and circulated in a reference country:

- The company shall be committed to submit an application to register the product under the fast track registration system via the e-mail: hm.appeal@edaegypt.gov.eg during the official working days and hours.
- The products file shall be revised by the Administration of Herbal Medicine Registration according to the list of the required documents. The company shall be notified of the acceptance or rejection of the application (In case of rejection, the reasons shall be indicated) via the e-mail within a period of three working days as a maximum from the date in which the application was received.
- In case that the company failed to fulfill any of the required documents, the file shall not be received, and the applicant shall be obligated to send an application to schedule a new appointment via the following e-mail of the Herbal Medicines Reception Section hm.appeal@edaegypt.gov.eg, within two months from the date in which the required documents were sent by the e-mail. This period is renewable for once.
- In case of the application is accepted, an appointment shall be scheduled to submit the final registration file,and the product stability file via the following email: hm.info@edaegypt.gov.eg and to pay the prescribed registration fees. That appointment shall take place in the next week.
- The initial revision shall be carried out by a representative of the Administration of Herbal Medicine Registration and a representative of the General Administration of Stability, provided that the companies shall be committed to provide storage conditions matching to those specified in the stability file.
- The company shall address the Pricing Department once the letter is sent to it indicating the approval of the request in order to complete the pricing procedures.

- In case that there are documents required to be fulfilled after examining the file by any of the aforementioned departments, the applicant shall be notified via the e-mail within 5 working days.

- The company shall be granted a grace period of one month as a maximum to submit required documents. This grace period is renewable for once and shall not be counted within the aforementioned registration period.
- When fulfilling all of the requirements from all of the concerned authorities, the time specified for evaluating the product shall be resumed.
- The file shall be presented to the Technical Committee for Drug Control to adjudicate on issuing a registration license. In case of approval, a valid for ten years final registration license shall be issued.
- The analysis required for registration shall be carried out at the Central Administration for Drug Control after obtaining the final registration license, on samples from the first imported consignment after the issuance of the final license. The competent administration is not allowed to release this batch until after issuance of the analysis results indicating the conformity.

Second: For the local products or manufactured under license products:

- The company shall be committed to submit an application to register the product under the fast track registration system via the e-mail: hm.appeal@edaegypt.gov.eg during the official working days and hours.
- The products file shall be revised by the Administration of Herbal Medicine Registration according to the list of the required documents. The company shall be notified of the acceptance or rejection of the application (In case of rejection, the reasons shall be indicated) via the e-mail within a period of five working days as a maximum from the date in which the application was received. In case of the response with the acceptance of the company's application, the product shall be directly presented to the Specialized Scientific Committee for Herbal Medicines whenever necessary in the next session in accordance with the applied rules.
- In case of approval, an approval of proceeding with the registration procedures shall be issued within five working days, and the company shall be committed to pay the prescribed registration fees before receiving of the approval.
- The procedures shall be completed simultaneously by the company.
- After completing all of the procedures, the company shall send a letter on the following e-mail hm.info@edaegypt.gov.eg to obtain a date to submit the final registration file within a period of 3 months from the date in which the last action took place by the company. In case of the company failed to fulfill any of the required documents, the file shall not be received, and the applicant shall be obligated to send a request to schedule a new appointment via the e-mail within two months from the date of sending the required documents by the e-mail. This period is renewable for once
- A grace period of 5 working days shall begin to be calculated from the date in which the file was received. After examining the file, the applicant shall be notified of any required documents via the e-mail within 5 working days.

- The company shall be granted a grace period of one month as a maximum to submit the required documents. This grace period is renewable for once and shall not be counted within the aforementioned registration period.
- The file shall be presented to the Technical Committee for Drug Control to adjudicate on issuing a registration license. In case of approval, a valid for ten years final registration license shall be issued.

Notes:

- ✓ **The deadlines granted to the company shall not be counted within the aforementioned registration period and the time specified for evaluating the product shall be resumed when fulfilling all of the required documents.**
- ✓ **For products that are still under registration and the company desires to complete the registration procedures in accordance with the system hereto, the company must submit an application to the Administration of Herbal Medicine Registration stating the company's desire to complete the registration procedures in accordance with the fast track registration system, the product's current status regarding the registration and the steps that have been completed, provided that the application shall be approved by the chairman of the company's board of directors.**
- ✓ **The application shall be studied and the product status shall be revised to ensure that none of the deadlines specified for completing the registration procedures have been exceeded, which would nullify the registration application. The fees of service and completing the procedures in accordance with the fast track registration system, shall be paid.**