nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY
مكتب الرئيس التنفيذي
Chief Executive Office

مملكة البحرين
Kingdom of Bahrain

Circular No. (26) 2023

Date: 30 October 2023

To: All Agents and Pharmaceutical Companies/MAH

Subject: Amendment of Resolution 32 on fast-track procedures for registration of all products.

Dear All,

Please be informed that NHRA through amendment of Resolution 32 have developed 2 fast track procedures for registration of all products.

1- **For products to be registered in 10 days the following should be submitted:**
   a. Product to be registered/approved in one of the below reference authorities:
      i. GCC central.
      ii. SFDA.
      iii. USFDA.
      iv. EMA.
      v. SwissMedic.
      vi. MHRA, UK.
   b. The Batch Releasing site should be registered with NHRA in the same above-mentioned authorities.
   c. Full e-CTD dossier of the product intended for registration same as what registered/approved in competent authority with complete assessment report from the same authority.
   d. With each application, a declaration letter from the company (MAH) stating that all information is correct and is as approved in the above-mentioned reference authorities.
   e. Payment of submission & licensing fees will be collected at the time of dossier submission.
      - Submission fees: 50/- BD through online payment.
      - Licensing fees: 300/- BD through online payment.

2- **Products not registered in the above listed authorities will be registered in 20 days under CONDITIONAL Registration – FAST TRACK), please note the following:**

After successfully submitting a full e-CTD dossier of the product intended for registration and paying the submission fees - Signed Checklist will be shared from the New Registration team.

a. With each application for condition registration submit the below:
    - Medicine Conditional Registration Application form.
    - Signed Checklist received from the New Registration team.
b. Product is **not required** to be registered in one of the reference authorities.
c. The Batch Releasing site should be registered in the below mentioned authorities.
    i. GCC central.
    ii. SFDA.
    iii. USFDA.
    iv. EMA.
    v. SwissMedic.
    vi. MHRA, UK.
d. Payment of submission & licensing fees.
    - Submission fees: 50/- BD will be collected during the submission appointment by registration team through online payment.
    - One year Licensing fees: 60/- BD will be collected within through online payment The license will be issued for 1 year, in which the registration requirements will be completed.
e. After 1 year, if the requirements are complete, the product will be registered for an additional 4 years paying the required fees – 240/- BD.
f. If the requirements are not completed, the conditional registration will be inoperative, and the product will not be registered without any notification.

For fees collection a new method of payment through IGA will be announced soon.

Appreciate your understanding & co-operation.

Dr. Mariam Athbi Al-Jalahma
Chief Executive Officer