nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

مملكة البحرين
Kingdom of Bahrain

Pharmacy & Pharmaceutical Product Regulation

International Manufacturing Site Licensing Procedure

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Table of Contents:

Item	Page
1. Introduction	**3**
2. General Notes	**3**
3. Submission & Documentation	**3**
4. Assessment and Queries	**4**
5. Licensing	**4**
6. Renewal	**4**
7. Application Fees	**4**
Annex 1: International Manufacturing Site Licensing/Renewal Checklist	**5**

1. Introduction

This document is meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. The document also provides assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Manufacturing site licensing is mandatory with NHRA prior to submission of application for new product registration or variation application pertaining to relevant site transfer.

It should be noted that the NHRA has the right to request any information and data within the context of this procedure.

This document should be read in conjunction with other applicable guideline documents.

2. General Notes:

The objective of this document is to define the procedure for licensing of international manufacturing site.

Listed below are few of the instruction vital for licensing process:

1. It is the responsibility of the applicant to ensure that all the information given in the approval checklist and supporting documents are true and valid.
2. Applicant must ensure that the submitted application form is signed and stamped.
3. Applicant in the application form refers to the marketing authorization holder (company).
4. Application should clearly indicate activity at the site (bulk manufacturing, batch release).
5. Bulk manufacturer in addition to batch releaser of sterile formulation should be registered with NHRA prior to submission of application for sterile product registration.
6. Batch releaser, technical release site should be licensing with NHRA prior to submission of application for product registration or variation application pertain to relevant site transfer.
7. Respond to NHRA queries or requests for more data for review, with in the timelines to avoid closure/rejection of the application.

Failure to comply with the above shall render the issued license cancelled.

3. Submission & Documentation

To submit new application, the applicant must request an appointment to the concerned staff in PPR department by email. Appointments are assigned on a first-come basis.

On the appointment day NHRA staff will check the file to make sure all the requested documents are available only valid applications will be accepted.

4. Assessment and Queries

Each application is assessed in accordance with relevant International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) quality guidelines. In cases where queries arise, a request for further information will be sent to the applicant. The applicant is requested to respond to such requests in a timely manner and in accordance with any decided timeline.

NHRA will not be held responsible for the delay of licensing process if the applicant fails to respond to NHRA request in a timely manner.

Failure to respond to NHRA request for information will result in rejection of the application.

5. Licensing

The license is valid for 5 years.

NHRA reserves the right to cancel or withdraw the license, if found non-compliant during its lifecycle after registration. Failure to register the products after site licensing within 3 years the license will be cancelled without prior notification.

Licensing of the manufacturing site with NHRA, do not circumvent the need for finished product registration. As per the Bahrain Pharmacy law 18 of 1997, pharmaceutical product must be registered with NHRA prior to its import/export, sale, and distribution in Kingdom of Bahrain.

6. Renewal

The renewal procedure will follow the same licensing procedure, however the documents required are highlighted in the manufacturing site check list annex1.

Applicant must ensure to submit a list of relevant variation (site name and address only) submitted in last 5 years. If not applicable, a declaration letter for the same must be submitted.

7. Application fees

As per resolution 17 of 2016, application fees and service fees are chargeable for each application submitted to NHRA. The applicant must refer to the latest fee structure from NHRA website

Annex I

International Manufacturing Site Licensing/Renewal Checklist

Agent name:			
Manufacturing site name:			
Type of application:	Registration ☐	Re-registration ☐	
1	Covering letter from the local agent in Bahrain signed.		☐
2	Letter from the company indicating the name and address of the manufacturing site and clarifying the relation between them (***Company letter head, signed***).		☐
3	Manufacturing site licensing/renewal form signed and stamped.		☐
4	Company profile (***SMF and other document to inform us about the company activities and responsibilities.***) #		☐
5	Copy of legalized contract between the company and the local agent (***pharmacy***) # including product list.		☐
6	Contact details for responsible persons at the company#		☐
7	Appointment Letter of the agent from the Company. #		☐
8	Copy of valid Certificate of registration of the company from the Ministry of Industry & Commerce. #		☐
9	Letter from the company declaring the name of medicine (s) released from this site (***Registered or to be submitted for registration***).		☐
10	Letter from the company declaring the activities performed at the site including batch release or bulk manufacturing.		☐
11	Copy of variations done since last 5 years relevant to the site's name and address only. (Applicable to renewal only) if no variation has been submitted a declaration must be submitted.		☐
12	Copy of Bahrain license (applicable for renewal only)		☐
13	Copy of valid GHC manufacturing site registration certificate. (***If the applicant cannot comply with this requirement, then copy of valid GMP certificate is required from one competent authority****)		☐
14	Copy of valid GMP certificate from health authority in the country of origin.		☐
15	Copy of valid Manufacturing License		☐
16	Proof of payment of the application fee (not refundable in case of rejection) #		☐
17	All documents to be submitted on CD		☐

*** Competent authorities (EUDRA GMP, HPRA Ireland, Germany, ANSM France, UK MHRA, USFDA, Health Canada, TGA, New Zealand Medsafe, Swiss medic, Japanese Ministry of Health)**

 # Required for registration of a new entity.

For Internal Use Only:

I declare that I have received the documents and materials confirmed in the above Checklist

Name:
Signature: _____ **Date:**
Comments: