nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Procedure for Pharmaceutical Facilities

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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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 provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent and effective.

This procedure has been developed to assist applicant for instruction related to licensing and other related activities of pharmaceutical facilities.

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.

Following are mandatory instruction as per the law:

1. Pharmaceutical facility license must be placed in clearly visible area in the facility.
2. The renewal application of the pharmaceutical facility license must be submitted at least one month prior to the expiration date of the current license.
3. If the pharmaceutical facility renewal application is not submitted in the first two months after the expire date, without a valid reason the license renewal fee will be doubled.
4. If the renewal application is submitted after two months of the expiry date, NHRA has the right to close the pharmaceutical facility.
5. The pharmaceutical facility is licensed to the individual named on the license, according to the law this license cannot be transferred to anyone else name, the license will become invalid, if the ownership of the pharmaceutical facility changes and new pharmaceutical facility license must be obtained.
6. The owner must have explicit approval from NHRA before any significant changes are made in the pharmaceutical facility.
7. As per the article 26 of the Bahrain pharmacy law number 18 of 1997 and its amendment no.20 of 2015, the pharmaceutical facility license will be cancelled in the following cases :
    a) The license has not been used for one year since the registration date without a valid reason approved by NHRA.
    b) If the pharmaceutical facility has been closed for more than a year without a valid reason approved by NHRA.
    c) The pharmaceutical facility is relocated without NHRA approval.
    d) If it is proved that the pharmaceutical facility is managed by someone other than the license holder.

2. Open New Pharmaceutical Facility

The installation of a new pharmaceutical facility has to be done in conjunction with Ministry of Industry Commerce and Tourism, Civil Defense, Municipality and NHRA.

Procedure:

1. The respective application for opening a new pharmaceutical facility is to be submitted via sijilat website https://www.sijilat.bh/
2. All the relevant required documents have to be uploaded through sijilat website.

3. Upon assessment, Ministry of Industry Commerce and Tourism shall issue an inactive CR.
4. The same application will automatically be received to NHRA for further assessment via sijilt website.
5. Upon assessment, NHRA will commence for inspection and the application fees for the same is required to be paid prior to inspection.
6. However, in event of any deficiency in document the applicant shall be requested to fulfil the deficient requirements.
7. Primary inspection shall be conducted according to inspection schedule.
8. Applicant should resubmit the application with conformation of successful preliminary inspection. NHRA shall grant approval for preliminary inspection.
9. Upon successful inspection the application will be transferred to the office of Civil Defense and Municipality.
10. The applicant must finish all process for pharmaceutical facility preparation e.g. all display/ receiving and must submit an application to NHRA requesting for final inspection.
11. NHRA shall sent communication informing the applicant of the date of final inspection via sijilat website.
12. Upon successful inspection the applicant is required to pay fees (as per the fees circular on NHRA website www.NHRA.bh) for license prior to issuance of license from NHRA
13. Ministry of Industry Commerce and Tourism will issue an active CR.

Renewal

14. An application is required to be submitted by the registered applicant of renewal at least month prior to license expiry. The application must be submitted at pharmaceutical regulation office (PPR office) in NHRA.
15. Upon successful assessment, the applicant must pay the required renewal fees prior to issuance to renewed license

Documents required:

1. Copy from old license
2. Copy of CR to be submitted with duly filled application form.

Note: Inspection will be subject to NHRA assessment.

3. Change Of Location

1. The application for change from one location to other should be submitted via sijilat website.
2. Upon assessment Ministry of Industry Commerce and Tourism will get the application approval for change.
3. NHRA will give an appointment for preliminary inspection of new location through sijilat
4. The applicant must declare stock status of the products including controlled & semi controlled and the methods of physical transfer must be declared in an official letter.
5. Final Inspection will be done as the NHRA schedule.
6. The applicant must surrender the original old license after final inspection. Approval will be

granted and new license will be issued after payment of the fees.

Note: The applicant cannot hold two license for the same pharmacy.

4. Addition Of Activity/Physical Change

1. The application for addition of an activity must be submitted via sijilat website.
2. Applicant must ensure, CR contains all activity served at the pharmaceutical facility.
3. Application for addition of activity will be assessed by Ministry of Industry Commerce and Tourism.
4. The application will be forwarded to NHRA via sijilat. Upon payment of fees NHRA will issue approval.
5. For Hypermarkets/supermarkets only: The applicant must add the activity of simple medicine (general sale) through sijilat website. The application will be then be assessed by NHRA. Upon successful assessment and payment of fees NHRA shall issue the license.

Note: No inspection will be conducted unless there is any major change in the physical pharmacy.

5. Change In Ownership

1. Application for change in ownership has to be applied via sijilat. Ministry of Industry Commerce and Tourism assess the application. The current owner will have to apply for cancellation of CR (no transfer allowed).
2. Through sijilat website, NHRA shall assess the application and the applicant will be informed for an appointment of inspection.
3. The applicant is required to close the pharmaceutical facility for business for a period of 24 hours.
4. An official declaration for pharmaceutical product stock in pharmaceutical facility including controlled and semi controlled products have to submitted.
5. Approval will be given for cancellation.
6. The new owner should submit for new owner pharmaceutical facility name at the same location and address in a new application form via sijilat website.
7. Approval from the office of Ministry of Industry Commerce and Tourism with new CR will be received at NHRA. NHRA, will give approval for the license after payment for fees.
8. The application will go to Ministry of Industry Commerce and Tourism for getting new CR with new owner.

Note:
1. Transfer of ownership without cancellation of CR is not permitted.
2. Original license with old name should be surrender to NHRA.

6. Closing Of Pharmaceutical Facility:

1. Application for cancellation of CR should be submitted sijilat website.
2. Upon assessment of application by Ministry of Industry Commerce and Tourism the application be assessed by NHRA.

3. An official declaration for pharmaceutical product stock in pharmacy including controlled and semi controlled product along with document on the outcome of existing products have to submitted.
4. Appointment for inspection will be given.
5. Original license must be returned back to NHRA.
6. Upon successful inspection an approval is given and CR will be cancelled or deleted.

Registration procedure of warehouse facilities for Pharmaceutical Product and raw material:

Important perquisite:

1. The applicant must be Bahraini or for a Bahraini company
2. The applicant must not be under any legal prosecution. However if the applicant in past has been in any legal case he/she must declare to have been freed from such case.
3. The warehouse should fulfil all the conditions and regulations as per the law.
4. All the pharmaceutical product to be imported, exported, distributed, stored or sold must be registered or approved by NHRA.
5. Authorized Pharmacist (Manager) is a must in warehouse.

Technical Requirements for the Pharmaceutical Products & Raw Materials warehouse:

Following is mandatory procedure to be followed.

1. The ware house should be physically located away from direct/indirect pollution.
2. There should be adequate space, light, ventilation and should suitable for work and storage.
3. The building should be made from concrete or Iron with good insulation. It should be equipped with doors and closure system.
4. The material used for construction should be easy in cleaning, safe to use, and protect the stored material from pest, insects, dust, smell and environmental changes due to heat, high temperature or humidity.
5. The warehouse should have more than one entrance for loading and unloading separate from the storage area and also have emergency exists.
6. The storage areas should be divided into receiving bays, delivery area. The storage area should have proper/suitable shelves, separate dedicated area for expired pharmaceutical products, damaged products until a decision is taken for it.
7. Name of the warehouse should be clearly written in both Arabic and English and must be displayed clearly in front of the warehouse.
8. The building should be air conditioned. The storage area temperature not increase above 25C, should have thermometers in different locations clearly defined.
9. The thermometers (heat/ humidity) should be placed in different locations, different heights in the warehouse according to temperature mapping study or to have one for every $50m^2$ of warehouse space.
10. International GDSP guideline should be implemented.
11. Cold room (2-8C) or refrigerator should be available in the storage area for pharmaceutical product that require cold storage, and should have thermometers to check the temperature, and must have a risk management plan in case of power failure.
12. A freezer for items should be available for product that require storage in low temperature, equipped with proper shelves and thermometer (automatic) which automatically record and be accessible for at least one year record and have a written announced risk management plan in case of failure.
13. To follow the instruction and conditions of Civil defense in the kingdom in case of storage of highly flammable and explosive items and to use mask for the staff.
14. In case the warehouse is licensed for storing narcotic and controlled, precursor items the below should be followed:

a) To be stored according to the standard and storage set by the manufacturing company
b) To be stored in closed cabinet/safe or specific store/warehouse for narcotic/ controlled/precursor items only. Well closed locked, no chance for break in or transport and to have security alarm system for protection.
c) To have specific record for each medicine and serialized pages and should have the following data written. in case of change the record should be signed :
    i. Name of medicine, pharmaceutical form and strength.
    ii. The previous balance
    iii. Incoming quantity and date
    iv. Outgoing quantity and date
    v. Total balance
    vi. The dispensed quantity, batch number, date of dispensing, to whom dispensed, and sign.
    vii. The beneficiary organization name and address
    viii. The balance quantity remained.
    ix. The record should be kept for at least 5 years and destructed only after the duration has passed by a committee made of 3 members and by decision of warehouse manager or his deputy and prepare a record for it.

15. Management offices could be attached to warehouse or separated.
16. The facility must have proper pest control system and record for it.
17. Safety measurements, firefighting systems should be available according to civil defense instruction in the kingdom.
18. Provide specific record system for the following:
    a) Incoming: Trade name, generic name, strength, pack, pharmaceutical form, invoice number & date, batch number. Expiry date and country of origin.
    b) Outgoing: Quantity, dispensed to whom, invoice number and date, quantity left, sign of dispenser, batch number, and manufacturing date.
19. The below shelf should be at least 15 cm from the ground and the top shelf away by one meter at least from the roof.
20. Barriers/Partition to be used to separate the different material from each other, proper ventilation should be provided to prevent contamination between these materials.
21. Keep a record file for all the approvals obtained from NHRA for importation
22. Proper air conditioned transport to be used for transportation and distribution
23. To have agreement with specialized company dealing with waste to get rid of expired, damage, medical waste pharmaceutical product or raw material.
24. Facilitate NHRA inspector's work in inspection of the warehouse at any time; to check the storage circumstances, take random sample and check any violation.
25. Prohibited to have any activity in the warehouse other than the authorized one, and the warehouse should not have direct or indirect contact with any other shop
26. To get approval from NHRA before selling, waiver of rights of warehouse, or doing anything and also in case of name change of the warehouse, or address change or the responsible person manager change.

Procedure for registration:

Documents required:

1. Application form from the website
2. Layout for the place & location
3. Lease agreement/ownership (contract)
4. CPR/ ID copy , passport copy (owner and Partner/s)
5. Pharmacist in charge license copy
6. Other authorities approval
7. Application fees payment receipt
8. Any other documents requested by NHRA.

Initial Approval

1. An initial inspection shall be conducted as per NHRA inspection schedule.
2. NHRA shall issue a pre-approval for the warehouse based on the inspection report to get the approval from sijilat website.

Intermediate step

1. The applicant must build and furnish as per the GDSP requirements on NHRA website
2. Apply (owner) for pharmacist license working in the warehouse.
3. The applicant must obtain other relevant authority approval and after all ready apply for final approval/ license.

Issuance of License

Upon final inspection, NHRA shall issue an inspection report. The License will be issued after the payment of the fees. The approval can be seen on the sijilat website as well.

Renewal:

It is mandatory to apply for renewal at least one month before expiry.
The penalty of late renewal is double renewal fees after expiry within 2 months. However after 2 months the application is consider new application and double the new registration fees.