



# Pharmaceutical Products Regulations in The Kingdom of Bahrain



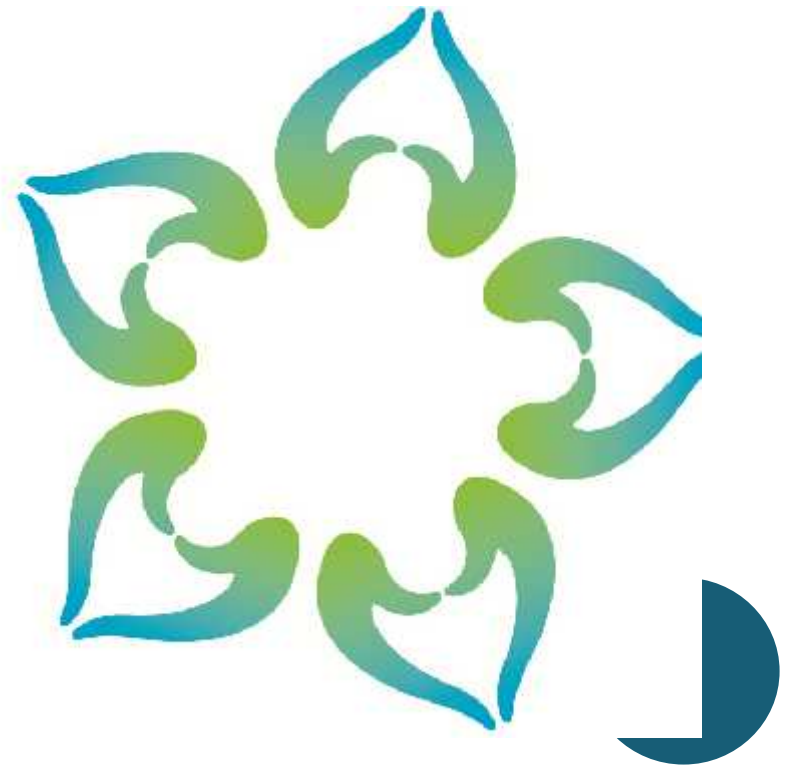
National Health Regulatory Authority



# ABOUT NHRA

The National Health Regulatory Authority (NHRA) an independent regulatory body established in 2010 under Law No. 38 of 2009.

Supreme Council of Health is our Management Board



# Vision

Safe and High-Quality  
Health Services



## Our Mission

Regulate the provision of healthcare in Bahrain to ensure high efficiency, safety and effectiveness in delivering health services; both in the governmental and private sector





# Goal 1: Regulated and accountable healthcare sector



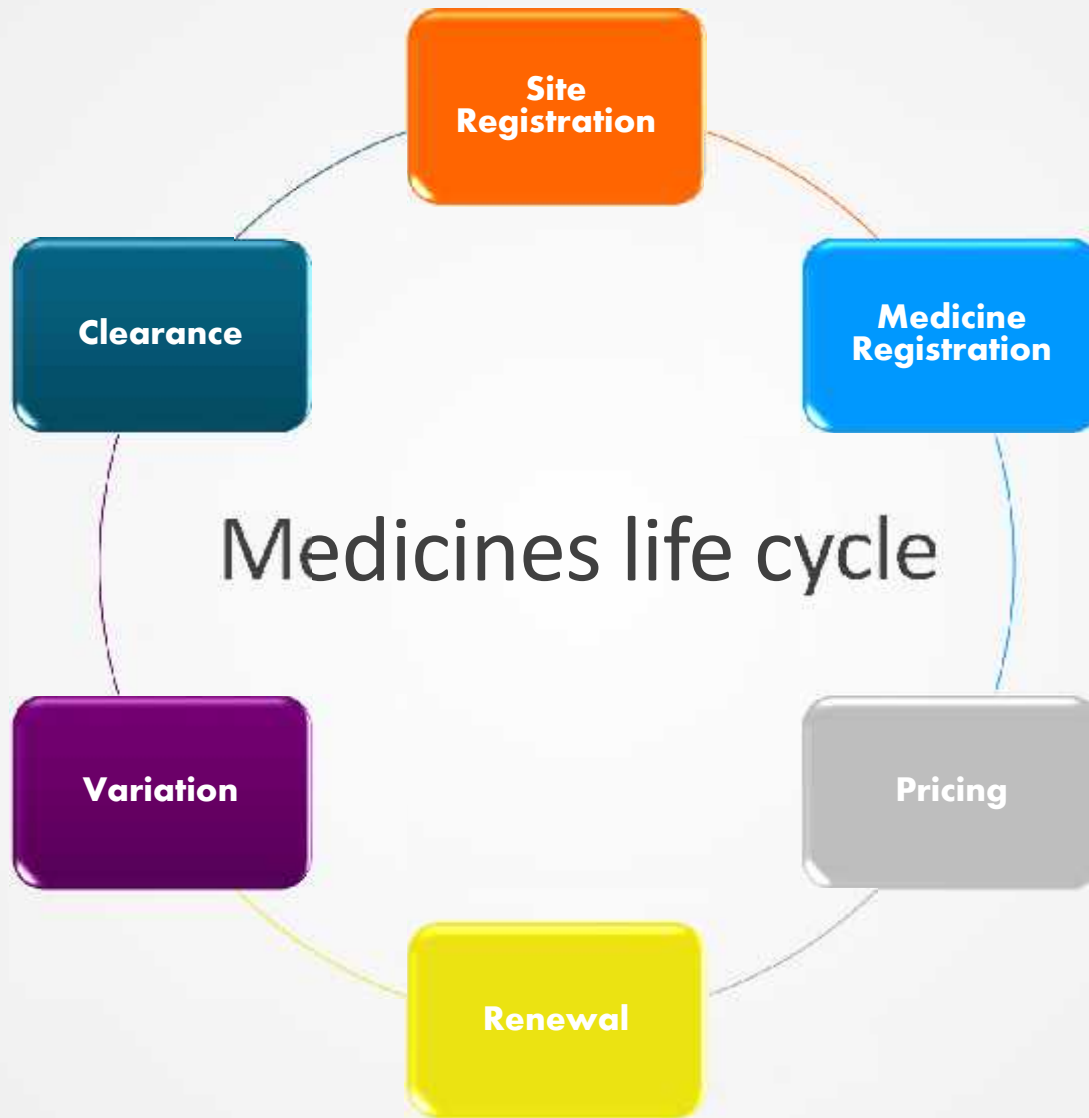
**Strategy 4**

Ensure the quality of medicines and pharmaceutical products

**Goal 1**

**Procedures**

Review all medicines and pharmaceutical products applications for registration /importation to ensure they meet the requirements before importation.



# Site Registration



Copy of valid Gulf Health Council(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\*)

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



# Medicine Registration Process



Service level agreement  
6 Months to 1 year

Fees:

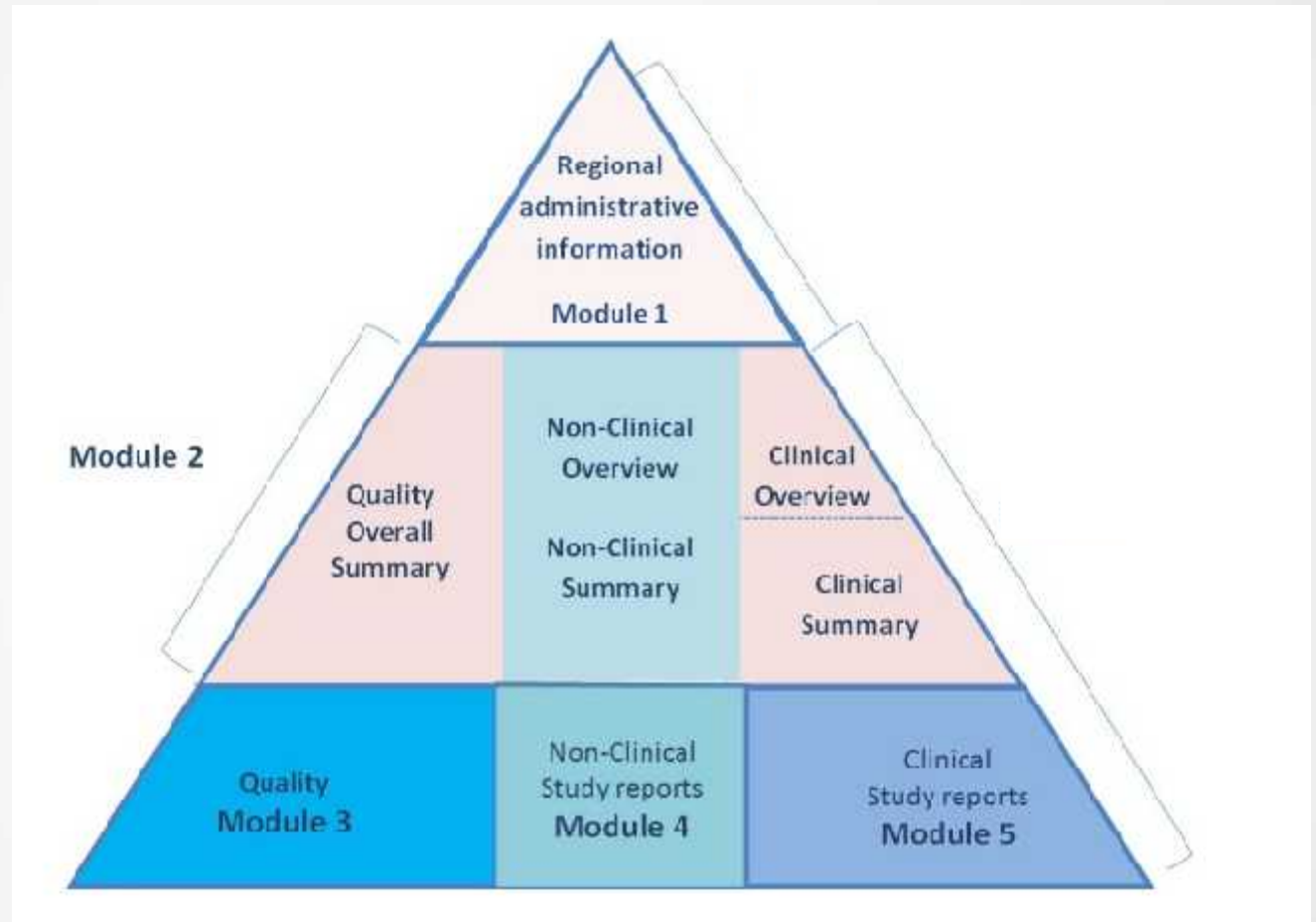
According to resolution 17 for 2020

Application fees paid once BD 50  
(132.63\$)

5 years registration fees 300 BD  
(795.80\$)

# Validation

Dossier in e-CTD format.





# Submission

## Module 1

Application form.

CPP.

GMP.

Manufacturing site registration.

Price Form.

Multiple API sources.

Multiple Bulk manufacturers, primary and secondary packagers.



# Assessment

Technical assessment of the dossier.  
Respond to queries within the time limit.






# Pricing

Mandatory for all medicines.

NHRA Pricing Guideline.





## Licensing Committee

Medicines licensing committee  
approval/acknowledgment.

Medicine license is valid for 5 years.



## **Circular No. (26) 2022**

**To: All Pharmaceutical Agents**

### **Sub: Facilitating Registration of Medicines**

To facilitate registration of medicines, NHRA will be accepting the submission of the registration dossiers for emergency and mature products with the minimum requirements, accordingly the following in CTD format:

- Module 1.
- Module 3.
- (BE Study, where applicable).
- Lab file (documents & samples).

# PPR Department online appointments

<https://outlook.office365.com/owa/calendar/PPR@nhra.bh/bookings/>





## Pharmaceutical Products Regulation Services

### SELECT A SERVICE

**Medicine Renewal**

It will make use the documents on account. [Read more](#)

15 minutes

**Medicine registration**

It will make use the documents on account. [Read more](#)

15 minutes

**Medicine Modification**

It will make use the documents on account. [Read more](#)

15 minutes

**Classification**

It will make use the documents on account. [Read more](#)

15 minutes

**Health Product**

It will make use the documents on account. [Read more](#)

15 minutes

**Alternative & Complementary Medicine**

It will make use the documents on account. [Read more](#)

15 minutes

**International Manufacturing site registration**

It will make use the documents on account. [Read more](#)

15 minutes

Show less services

Select a service to see available dates and times

Select a service to see available dates and times

### SELECT START (OPTIONAL)

Anyone

### DATE

September 2022

| Sa | Su | Mo | Tu | We | Th | Fr | Sa |
|----|----|----|----|----|----|----|----|
|    |    |    |    |    | 1  | 2  | 3  |
| 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 |    |    |    |    |

### TIME

Select a service and date to see available times

### ADD YOUR DETAILS

First and last name

Notes (optional)

Email

Address (optional)

Phone number (optional)

Book

The Policies and Conditions of Pharmaceutical Products Regulation Services apply to the use of your data

# Conditions for Importing Non-Registered Medications

## ❖ For Government and private sectors



## ❖ For Local Agents



# Importation/ Clearance Process

Submit application  
on (DUR)



```
graph TD; A[Submit application on (DUR)] --> B[Pay the fees]; B --> C[Approval issued];
```

Pay the fees

Approval issued

Service level agreement  
2 working days

Fees:  
500 Fils (1.33 \$) for each  
product clearance

www.nhra.bh

The image shows the homepage of the National Health Regulatory Authority (NHRA) in Bahrain. At the top, there is a navigation bar with a search field, a 'Covid-19' button, and links for 'Your Opinion', 'Sitemap', and social media icons. Below the navigation bar is the NHRA logo and name in both Arabic and English. A main menu includes 'HOME', 'ABOUT US', 'DEPARTMENTS / SERVICES', 'MEDIA', 'HIC', 'OPEN DATA', 'ENHRA APPLICATION', and 'CONTACT US'. The central part of the page features a large group photo of NHRA staff. Overlaid on the photo are four statistics: 593 total health products registered, 3643 total medications registered, 145 alternative and complementary medicines approved, and 7 COVID-19 vaccines authorized. At the bottom, there is a row of eight service icons: Professionals License Regulations, Facilities License Regulations, Pharmacies License Application (highlighted with a red box and a red arrow), Pharmaceuticals Application, Medical Devices Application, CME Application, Clinical Trials Application, and Complaints / Incidents Reporting.

nhra  
BAHRAIN  
الهيئة الوطنية لتنظيم الممارسات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY

HOME ABOUT US DEPARTMENTS / SERVICES MEDIA HIC OPEN DATA ENHRA APPLICATION CONTACT US

593  
total number of health products registered in the Kingdom.

3643  
total number of medications registered in the Kingdom.

145  
number of alternative and complementary medicines approved.

7  
total number of COVID-19 vaccines emergntly authorized

357  
total number of new medications registered

PROFESSIONALS LICENSE REGULATIONS

FACILITIES LICENSE REGULATIONS

PHARMACIES LICENSE APPLICATION

PHARMACEUTICALS APPLICATION

MEDICAL DEVICES APPLICATION

CME APPLICATION

CLINICAL TRIALS APPLICATION

COMPLAINTS / INCIDENTS REPORTING

## Pharmaceutical Products Regulation (PPR)

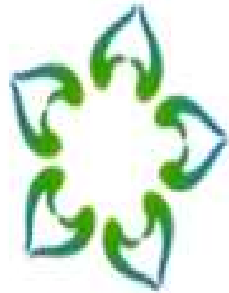
- Overview
- News
- Regulations
- Circulars
- Classification
- Manufacturers & Distributors
- Medicines**
  - Guidelines & Procedures
  - Applications
  - List
  - Contacts & Appointments
- Health Products
- Alternative & Complementary
- Pharmaceutical Facilities
- Importation and Clearance
- Fees
- Useful Links
- Contacts



In Bahrain, the Pharmaceutical Products Regulation Department (PPR) of the National Health Regulatory Authority (NHRA) ensures in so far as possible, in consistent with current medical and scientific knowledge, the quality, safety and efficacy of pharmaceutical products, including medicines, health products, and alternative/complementary medicines in the Kingdom of Bahrain.

Before a pharmaceutical product can be sold in Bahrain, an application must be made to the NHRA and this must contain all of the necessary data supporting its quality, safety and efficacy, based on the current guidelines and procedures. PPR members review the scientific aspects of each application and reach a conclusion on the likely balance of any benefits versus risk before arriving at a decision.

nhra  
BAHRAIN



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY



## NHRA-Drug Track and Trace system



# Legislative Decree No. 41 of 2017

nhra  
BAHRAIN



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY



Official Gazette

No. 3342 – Thursday 30 November 2017



Supreme Council of Health

Legislative Decree No. 41 of 2017

Issuing a Track and Trace System for the Supply Chain of Medicine within the Kingdom of Bahrain

The President of the Supreme Council of Health:

Having reviewed Law No. (19) of 1997 with respect to the Practice of Pharmacists and Pharmaceutical Centers, as amended by Law No. (25) of 2015,

Law No. (38) of 2009 regarding the establishment of the National Health Regulatory Authority (NHRA), as amended by Law No. (32) of 2015,

Legislative Decree No. (5) of 2013 establishing the Supreme Council of Health and its amendments,

The Regulations for the Medicine Registration System in the National Health Regulatory Authority (NHRA) promulgated by Legislative Decree No. (12) of 2016, as amended by Legislative Decree No. (8) of 2017,

And to ensure the quality of medicines in the Kingdom of Bahrain,

And based upon the submission of the Chief Executive Officer of the National Health Regulatory Authority (NHRA), and

Subsequent to the approval of the Supreme Council of Health.

## Article (1)

gives the National Health Regulatory Authority (NHRA) the authority and obligation to apply the Track and Trace system for the supply chain of medicine within the Kingdom of Bahrain **from the manufacturing site to the patient** (Track and Trace) in accordance with the bylaws and regulations attached hereto.

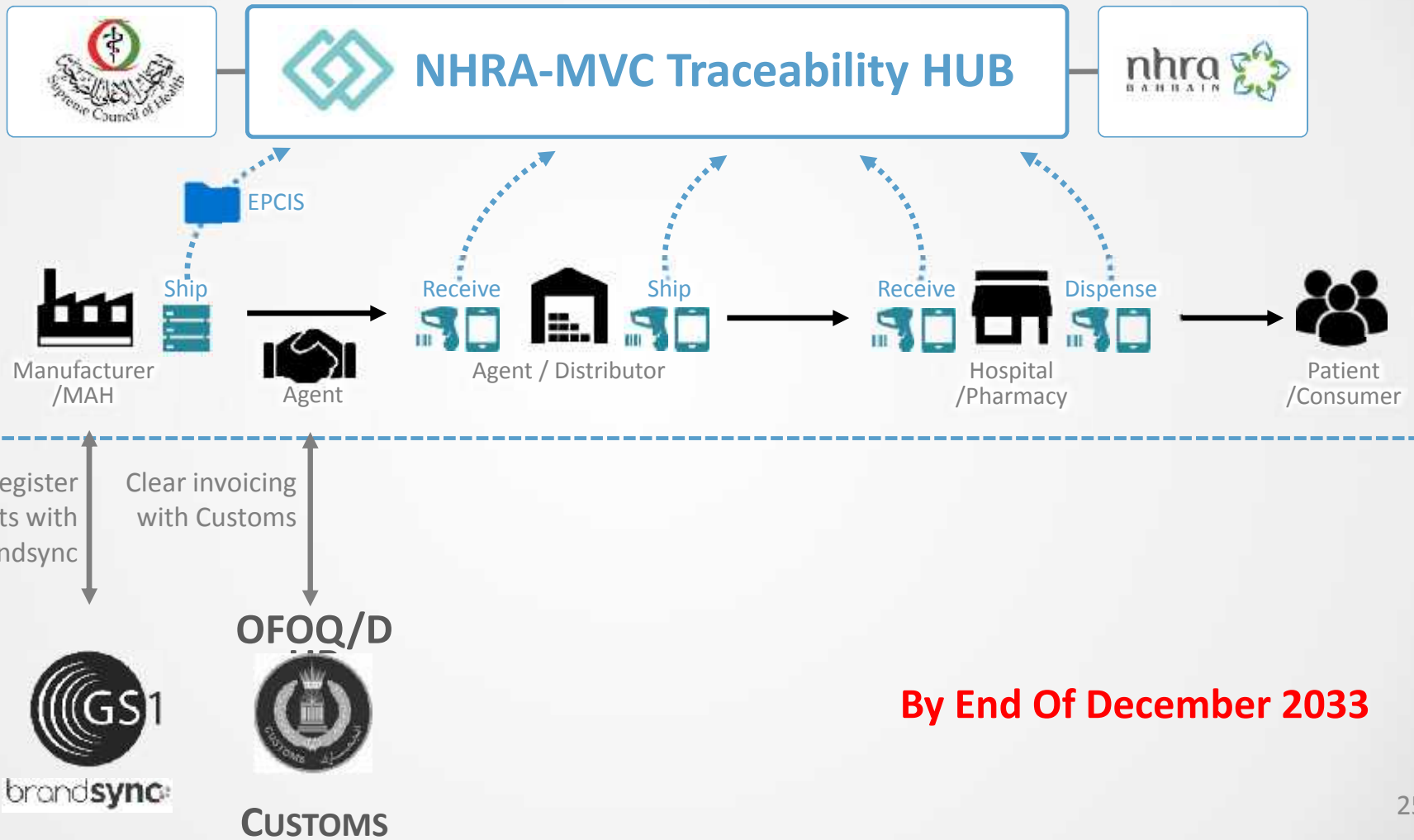
Use of the Trace and Trace system is required for all Manufacturing sites, companies, distributors, importers and storage keepers of medicines, pharmaceutical products and pharmaceutical institutions of all kinds.

## NHRA Purpose & Goals



- End-to-End traceability hub for all drug imports to Bahrain
- Complete visibility of various stages of supply-chain from manufacturing companies to agents/distributors to pharmacies/hospitals
- Central repository of all real-time information flow and accurate inventory data throughout the supply-chain among all stakeholders
- Increase patient safety
- Help detect counterfeit drugs
- Analytics of drug imports and consumption in Bahrain
- Manage product recalls and shortages efficiently and timely







NHRABahrain



Nhra-Bahrain



Nhra\_bahrain