



# NHRA NEWSLETTER

APRIL 2016

## CLINICAL TRIALS REGULATIONS

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NHRA held the first joint scientific forum on clinical trials titled "Capacity-building and encouraging responsible behavior for clinical trials." the forum was held in partnership with the Arabian Gulf University. Private and government hospitals have participated in the forum, beside pharmaceutical companies.

The forum discussed adopting national criteria and standards to be followed by ethics research committees for approving clinical trials in health care facilities.

We had a very positive interaction from the participants.

All the recommendations will be taken into consideration when drafting the final national standards.



## A NEW 5 YEAR STRATEGIC PLAN FOR NHRA

The recent challenges in regulating the growing health sector in Bahrain, require revision and update of the previous NHRA strategy to respond to all the challenges. Among the most important strategic goals are: to move towards excellence in regulatory performance, ensuring safe practice and safe medicines. The new 5

year strategic plan will be developed to overcome the risks and challenges, and to ensure compliance with the regularity laws. While working on our new strategy, we strive to eliminate the risks facing us such as lack of financial and human resources, and lack of some standards regulating the health care services. NHRA is dedicated to achieve its vision **“Safe, trusted, high-quality and effective**

## COMPLEMANTRY & ALTERNATIVE MEDICINE TO BE REGULATED

The recent increase in demand for complementary and alternative medicine (CAM), stipulates the development of national standards and regulation for such practice. NHRA will ensure that CAM practice is in accordance with international standards to maintain patient

safety. All CAM practitioners were invited to a meeting held by NHRA to discuss the development of the new standards and regulations. We had a great input from the participants, all obstacles and challenges have been taken in consideration when developing the standards. NHRA wishes

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## A UNIFIED GCC REGULATIONS FOR CAM

NHRA sponsored a GCC meeting in April to adopt unifying CAM regulations in the member states. The unified GCC regulation proposed by NHRA standardize the requirements for licensing CAM Facilities, alternative products, and practitioners.

The following practices will be regulated among others in the GCC:

- Acupuncture**
- Ayurveda**
- Chiropractic**
- Homeopathy**
- Naturopathy**
- Osteopathy**
- Traditional Chinese Medicine**
- Unani practice**
- Hijama therapy**



## REGISTRATION OF MEDICINES AND PHARMACUTICAL PRODUCTS

Pharmaceutical products regulatory section has reviewed on over 4800 product, included in various activities as listed below. The registration processes have been shortened to 6 months provided that all the required product documents are submitted. Products that are centrally registered in the GCC office are accepted as fully registered in Bahrain and the registration process takes less than one week. If the product has FDA, HEALTH CANADA, EMA, SWISS-MEDIC, SDA, Kuwait, Oman or UAE approval, it will then be granted a temporarily permission, with a one year period to complete the local registration in Bahrain.

<b>Drug regulatory section activities (Jan-March 2016)</b>	
<b>Variations</b>	<b>113</b>
<b>New Drug registration</b>	<b>42</b>
<b>Renewal of registration</b>	<b>75</b>
<b>Manufacturing site registration</b>	<b>21</b>
<b>Health Products</b>	<b>48</b>
<b>Functional Food</b>	<b>13</b>
<b>Product Classification</b>	<b>116</b>
<b>Product Destruction</b>	<b>3</b>
<b>Local Inspections</b>	<b>67</b>
<b>GCC Inspections (GMP)</b>	<b>5</b>
<b>Pricing (Average)</b>	<b>17</b>
<b>Safety &amp; Warning</b>	<b>4</b>
<b>Parcels (Average)</b>	<b>800</b>
<b>Invoices (Average)</b>	<b>1,470</b>
<b>Approval for Non Registered Pharmaceutical Products</b>	<b>484</b>
<b>Pre-Approval</b>	<b>1596</b>

### EMPLOYEE OF THE MONTH ROAAYA ALABBASY



### CHIEF OF PHARMACEUTICAL REGULATIONS

July 1990 Bachelor Degree in Pharmacy - King Saud University (S.A)  
 Feb. 2003 CIPS Certificate in Purchasing and Supply (UK)  
 (Chartard Institute Of Purchasing and Supply)  
 Aug. 2004 Advanced CIPS (UK)  
 Nov. 2007 MBA Glamorgan University (UK)

1991 – Join BDF as a Trainee  
 1992 – Join BDF Pharmacy

1995 – Head of Narcotic Drugs in the Pharmacy

1996 – Senior Pharmacist

2001 – Head of Medical Material Supplies (Drugs, Laboratory, X-Rays, Dialysis, IVF)

2010 – Director of Material Management in King Hamad University Hospital

2013 – Chief Pharmaceutical Product Regulation (NHRA)

till to date



## ONLINE APPROVAL FOR IMPORTATION OF MEDICAL

In coordination with the Department of Customs, NHRA started introducing licensing for import of medical devices electronically, through the application of "OFOQ" system. This online program will enable importers to receive

approval before the arrival of shipments. The system allows uploading of documents required for a license electronically through the program, which facilitates and speeds up the clearance process. 2832 packs and boxes have been released through the system in February and March of this year.



## NATIONAL ACCREDITATION OF HOSPITALS

NHRA is dedicated for ensuring that health services in the Kingdom of Bahrain meet international standards. Our mission is to be a continuous driver for safer patient care and establish a culture of continuous improvement in all healthcare facilities in the kingdom. Article (19) of the law number 21 for the year 2015, states that NHRA to carry out annual evaluation of all health care facilities against adopted national standards.

The national standards address the care of individuals in the hospital environment and are designed to facilitate the provision of safe care. The standards identify core, support, and specific elements.

The core elements will be applicable to all hospital facilities, while the support elements will be assessed as being applicable or not applicable and implemented accordingly, and the facility specific elements are only assessed in the hospitals that provide the services identified.

The National standards are published on NHRA web site. NHRA will partner with Saudi center for accrediting health care facilities (CBAHI). CBAHI will support NHRA in the evaluation, training and Capacity building.

**MEETING WITH PRIVATE HOSPITALS**

NHRA met with all private hospital directors to discuss the upcoming national accreditation process. The hospital directors expressed their appreciation for NHRA’s approach to involve the private sector in the their views in the implementation process. They have observed the recent remarkable improvement in NHRA regulations and processes, which were reflected on the speed of the licensing process and procedures.



**HEALTH FACILITIES CLASSIFICATION**

Based on the results of Hospital accreditation, hospitals will be classified according to international standards. The classification will take into consideration the performance of the hospital based on a set of national standards. This method has the advantage of tying hos-

pital classification with performance using objective criteria for such classification. It also encourages hospitals to seek higher levels of classification regardless of size, location or scope in order to attract more revenue and achieve better reputation.

Here is a suggested model for such classification:

- Grade D or SILVER** hospitals with a compliance score of at least 70% but less than 80%
- Grade C or GOLD** hospitals with a compliance score of at least 80% but less than 90%
- Grade B or PLATINUM** hospital with a compliance score of at least 90% but less than 95%
- Grade A or DIAMOND** hospital with a compliance score of 95% or higher

**INFECTION CONTROL WORKSHOP**

NHRA have conducted a workshop on infection control procedures that should be adhered to in dental clinics. The workshop was organized jointly with Ministry of Health’s infection control section. More than 40 participants have attended from the private sector. Policies and procedures of infection control was discussed. The workshop included both theoretical and clinical training. Needs were identified and discussed.

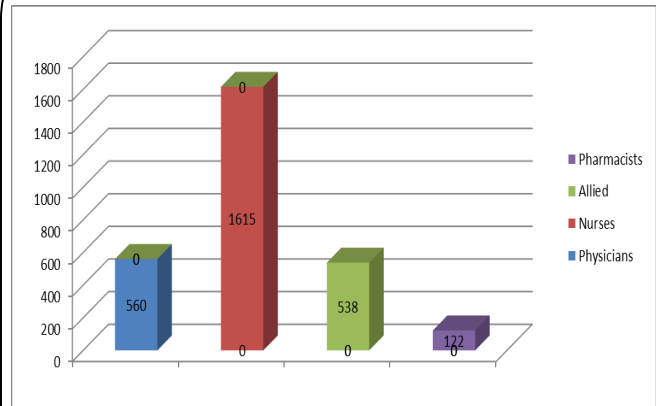


## FIRST QUARTER STATISTICS

### Pharmacies and health products facility Licenses

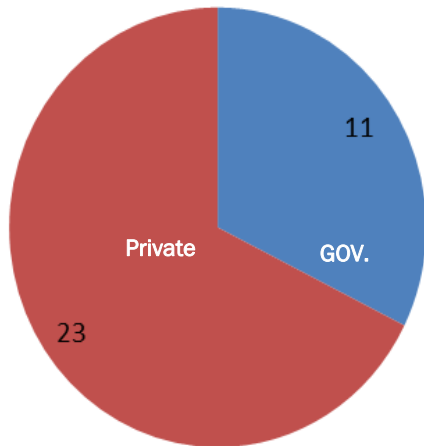
- ⇒ Renewals of Pharmacies licenses: 40
- ⇒ New Pharmacies licenses : 5
- ⇒ Renewals of health product licenses: 15
- ⇒ New health product licenses : 8
- ⇒ Issuing Pharmacy Payments: 70
- ⇒ Issuing health product Payments : 60

### Professionals licensing Jan- March 2016

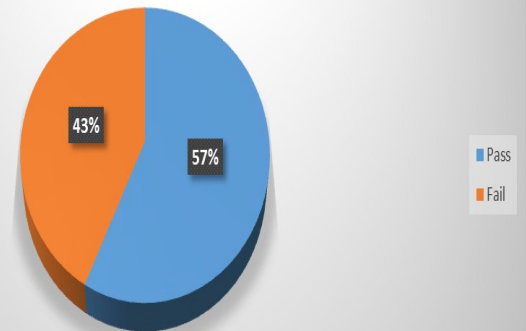


**2715 licenses have been issued**

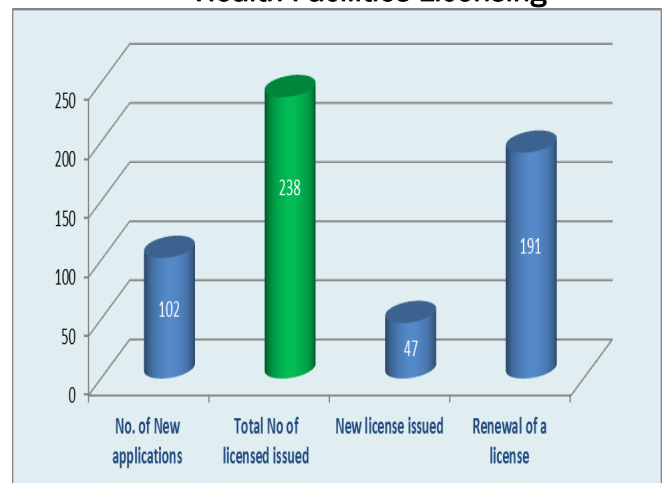
### Complaints reported from Jan.-March



### Medical Profession Licensure Exam Results



### Health Facilities Licensing



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