



1 February 2016
Volume 1, Issue 1

NHRA NEWSLETTER

Welcome to our first Issue of NHRA newsletter. Our newsletter will keep you updated with all NHRA news, and will highlight our new activities and decisions. Read inside; the new orders issued by supreme council of health and the CEO.



**Her excellency the minister
of Health
visits NHRA**



**His excellency Dr. Khalid Al-Ohaly
The president of AGU & NHRA CEO**



INSIDE THIS ISSUE

From the CEO	2
New Laws Issued	3
Licensure Exams fixed.....	3
Regulating Clinical Trials	3
SCH Decisions	4
CEO Orders.....	4
Online Services	5
Regulating medicines	5
NHRA Statistics.....	6

FROM THE CEO



We look forward to the year 2016, as we hope it will witness many changes in our policies and procedures.

Since the Supreme Council of Health has become our management board, many of our functions have been re-visited.

The previous Board worked hard to develop the infrastructure of NHRA's functions, and have set out basic rules for regulating the health sector in the Kingdom of Bahrain, but the upcoming development in health care financing and regulation, in light of applying social health insurance system, will require an advanced role for NHRA to be part of those developments.

While we review our policies and procedures, we bear in mind our partners in the public and private sector, whom we will be working closely with, and we will work hard to update our system in order to facilitate our procedures without prejudice to quality standards.

We have already established online approval for health facilities licensing through Ministry of Industry and Commerce web page, using *BLIS* program. And very soon we will link with *OFOQ* online costumes' program to approve release of drugs and medical devices.

Among the most important future steps, NHRA would seek, is to develop a 5 year strategic plan that aims to complete its administrative and legal systems. This strategy will support NHRA to perform its mission to the fullest. We will develop our internal and financial regulations, as well as setting standards and licensing requirements for all types of health facilities, including setting up licensing standards for alternative medicine and IVF centers. We will be working on developing national criteria for licensing physicians, and allied health professions. NHRA will also conduct a comprehensive development of its website to include online applications for obtaining a license for all professionals, and conducting licensure examinations.

We face a number of challenges ahead of us, but the opportunities we have are greater and will enable us to achieve our vision;

“Effective safe, reliable, and high-quality health care”

Dr. Mariam AL-Jalahma

Employee of the Month



Dr. Leena Al Qassim

Dr. Leena has been nominated by the incentive & promotion committee at NHRA as employee of the month. She is currently holding the position of Chief of Professionals Regulation. She joined NHRA in 2012 and was holding the position of Chief of Complaints.

Dr. Leena graduated from *Royal College of Surgeons in Ireland (Dublin/Ireland)* in 1995. She holds

Master's of Science specialization in Bioethics from McGill University, Canada 2003 and Professional Doctorate in Medical Ethics (DMedEth) from Keele

Licensure exams dates to be fixed annually

NHRA has conducted since December 2015, three licensure exams for medical doctors, dentists and pharmacists. The success rates were 60%, among doctors, 64% among dentists, and 68.89% among pharmacists.

The exams will be scheduled as followed for the year 2016:

Medical doctors March, September

Dentists May, September

Pharmacists May, September

Nurses

May, September

Our future plan is to conduct the exams electronically



Regulating Clinical Trials

The CEO has issued an order to regulate clinical trials conducted in the kingdom, this committee will be responsible for clinical research requests referred to it by the CEO, and raise its recommendation accordingly. It will monitor the implementation of all phases of clinical research, to ensure conformity with the

Rules, technical requirements and scientific standards .

All pharmaceutical companies, Hospitals and physician are required to submit their research before implementation.

NHRA is currently working to develop guidelines for implementing clinical trials by mid of this year.



Legislative decrees issued in 2015

New legislative laws has been issued by his majesty the King of Bahrain in the last quarter of 2015, they are namely:

- Decree No. (41) of 2015 on the restructuring of the Board of NHRA
- Decree No. 32 of 2015 on amending Law No. 38 of 2009, on the establishment of NHRA
- Decree No. 20 of 2015 amending some provisions of Law No. 18 of 1997 concerning the regulation of the profession of pharmacy and pharmacy centers.
- Decree No. 21 of 2015 on private health institutions.

The new laws do not only regulate NHRA's functions, but they facilitate investment in health care sector in the Kingdom.

Orders issued by the Supreme Council of Health SCH

The SCH has taken a number of decisions to regulate some of NHRA's functions and procedures, those decisions include:

- Regulating Medicine and pharmaceutical products registration
- Regulation for disciplinary committees
- Regulating licensure exams for health professionals
- Transferring the authority for licensing narcotic drugs to the ministry of Health
- Establishing two committees to develop standards and classification of medical doctors and dentists, with an aim to adopt a common national standard.
- Regulating the licensing of Health and Functional food products
- Regulating over the counter medications

Supreme Council Of Health



Orders Issued by the CEO

- Formulating the Advisory Committee for licensing medical professionals
- Establishment of a committee for approving clinical Trials.
- Establishment of NHRA's training committee
- Establishing the Equal Opportunities Committee in NHRA
- Establishing NHRA's incentive and promotion committee
- Establishing the Committee for licensing private health facilities.

NHRA Celebrating the National Day



Regulating registration of medicines and pharmaceutical products in Bahrain

A new order number (12) for the year 2015, was issued by His Excellency Sheikh Mohammed bin Abdullah Al Khalifa, the President of the Supreme Council of Health, to organize the registration and trading of medicines and pharmaceutical products in the Kingdom. According to this new order, it is mandatory to register any medicine in all its forms. Applications will only be accepted after the adoption of pharmaceutical manufacturing sites according to the standards adopted by the Gulf Cooperation Council (GCC).

Medicines and pharmaceutical products will be priced according to GCC price list or CIF price.

Importing unregistered lifesaving drugs by hospitals

The new order also determines the list of lifesaving drugs to be permitted to import without registration, which are used to treat some emergency and critical hospital cases and does not have a registered alternative in the Kingdom.

New drugs import authorization has a fast track

The new order has authorized new drugs to be imported to the kingdom of Bahrain if they have been approved by FDA, HEALTH CANADA, EMA, SWISSMEDIC, SDA, Kuwait, Oman or UAE.

The authorization will have a limit of one year period to complete the registration requirements.

Drugs registered centrally in the GCC executive office will be considered as fully registered in Bahrain.

Meeting with the Health committee in Trade & Commerce Chamber to discuss joint Issues

Online costumes release for medical equipment devices and Drugs coming soon

NHRA has finalized its cooperation with costumes to link through OFEQ online program to give release approval for medical devices and drugs. This process will certainly give a solution to the delay in the

On line application for Health facilities

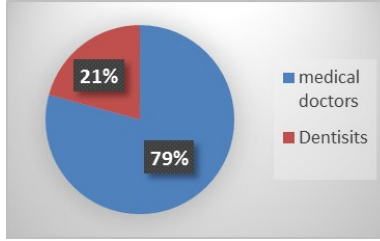
Investors are able now to apply on line through BLIS program on Ministry of Industry and Commerce (MOIC) web site. NHRA has finalized cooperation with MOIC to give preliminary approval to open a health facility by applying to MOIC BLIS program. Investors should later on apply to NHRA the proposal plan for the health facility they intend to run, once approved they can start establishing their facility, and the final approval will be given once they finish the full project.



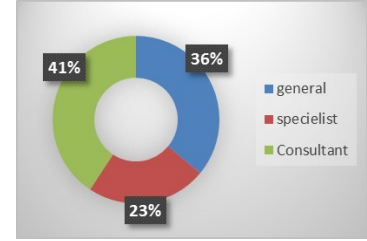
Medicine & Pharmaceutical Products Regulation activities

Activity	Number
Changes on drugs	421
Drug registration	132
Renewal of registration	425
Registration of pharmaceutical companies	59
Registration of pharmaceutical products	140
Reiteration of HELATHY FOOD PRODUCTS	120
Product categorization	51

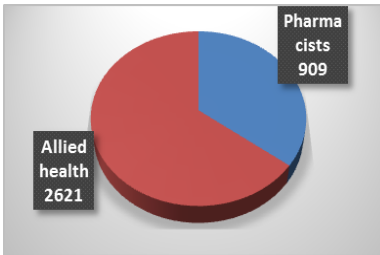
Registered Medical doctors and dentists



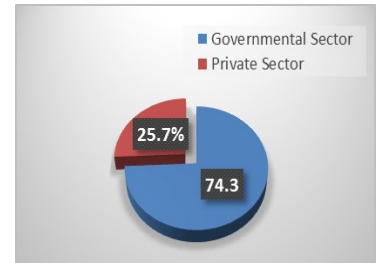
Physician's Categorizations



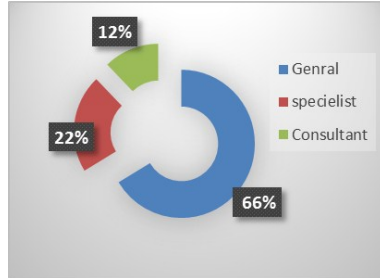
Registered Pharmacists & Allied Health



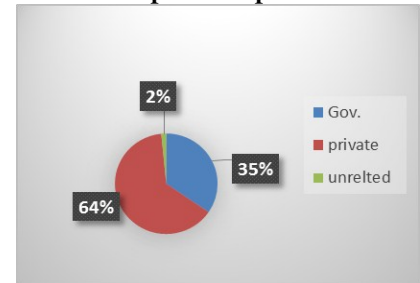
Registered Nurses



Categorization of registered dentists



Complaints reported



National Health Regularity Authority

Phone: +973 17 11 33 31
 Fax: +973 17 11 33 59
 E-mail: ceosecretary@nhra.bh
 www.nhra.bh



Distribution of Registered Health Facilities

Health Institute	southern	Northern	Moharraq	Capital
Hospital	3	1	1	13
Dental Hospital	-	-	-	2
Specialised medical centre	6	3	6	22
General medical centre	2	4	3	7
Dental centre	1	10	8	17
24 hour clinic	-	-	-	2
Regular Clinic	3	-	18	3
Part time clinic	-	-	4	14
24 hour dental clinic	-	-	-	3
Dental clinic	3	4	3	30
Part time dental clinic	-	-	-	1
24h paediatric clinic	-	-	1	1