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الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY



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NATIONAL HEALTH REGULATORY AUTHORITY

**Report  
2016**



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**The CEO with National Health Regulatory Authority (NHRA) Advisors**  
NATIONAL HEALTH REGULATORY AUTHORITY

***Our ambition is to international reach competitiveness  
in regulating the health sector in the Kingdom of  
Bahrain***

### ***From the SCH Chairman***

In the year 2016, The National Health Regulatory Authority (NHRA) was able to demonstrate remarkable achievements in its regulatory policies and procedures. We are expecting even further improvements by implementing the new five year strategy plan which will enable NHRA to reach global competitiveness in regulating the health sector in the Kingdom.

We seek to strengthen and support the role of NHRA to be able to perform its task as an independent regulator, for both government and private sectors, by overseeing implementation of best practices at all levels of healthcare services in the Kingdom of Bahrain.

As we move forward to implement the national health insurance system, the presence of a strong and well-regulated health sector will contribute favorably to the success of this major milestone all the while creating an encouraging environment for health care investments.



“We seek to strengthen and support the role of NHRA to be able to perform its task as provided for by the law of its establishment; both in the governmental and private sector based on the best scientific principles and health practice standards accredited in the Kingdom”.

***His Excellency Lieutenant General Dr. Sheikh Mohamed Bin Abdullah Al-Khalifa Chairman of the Supreme Council of Health***

## **From the CEO**

The National Health Regulatory Authorities vision is to provide safe, trusted, high-quality and effective healthcare to the people of Bahrain. We regulate the healthcare system to ensure that the people of Bahrain experience a service that protects and promotes health. One of our fundamental roles as a steward of the health care system is to ensure the system as a whole delivers the best possible healthcare outcomes for the people of Bahrain.

The National Health Regulatory Authority (NHRA) saw many new developments in 2016 that have paved the way for us to achieve our vision, starting with the revision of our strategic goals. In the last 12 months, we have focused on refining our strategy keeping in mind our overarching vision which is to ensure that safety and the highest quality is central to the delivery of health care in the Kingdom of Bahrain. We aim to achieve our vision through three strategic goals:

- **Regulate and Hold Healthcare Facilities Accountable:** *To ensure that all healthcare facilities meet the required standards for licensing.*
- **Provide Safe and Trusted Healthcare Services:** *A commitment to continuously monitor the quality of healthcare services to ensure compliance with evidence-based practices and accreditation standards.*
- **Preserve the rights of patients and make patient safety a priority:** *To protect the rights and the safety of all people who use health care services and facilities in the Kingdom.*

Furthermore, fulfillment of these strategies will lead the way for implementation of the upcoming social health insurance system and create an encouraging environment for health care investments.

In 2016, several departments of NHRA reevaluated regulations and procedures. Work flow processes such as professional and facility licensing, medical devices clearance and drug registration were revised to make them

more in line with international standards of efficiency and effectiveness. This move has been seen very favorably by our clients and stakeholders in the Kingdom.

Finally, the end of 2016 saw the emergence of a new era for standards of healthcare in the Kingdom of Bahrain. NHRA accreditation surveyor training started in December where 56 esteemed members from the healthcare community in the Kingdom and 30 staff members from NHRA were selected to attend a workshop presented by senior surveyors from The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI). Qualified surveyors will be part of a multidisciplinary team that will implement the accreditation process to private hospitals in 2017. By achieving NHRA accreditation, healthcare facilities can demonstrate that they have undergone a rigorous assessment and have met international standards in patient safety and quality.

#### **Achievements in 2016:**

I am pleased to say that, while there has been significant focus on the future direction of the healthcare system, NHRA has achieved and implemented 70% of its initiatives that were set forth in 2015 which have now become an integral part of the 5 year (2016 – 2020) healthcare plan. These achievements included:

1. Establishment of NHRA: 2016-2020 Strategy.
2. A 40% increase in staff from 2015 to 2016.
3. Development of NHRA's financial by-laws in collaboration with the Ministry of Finance.
4. Revision and publication of all NHRA fees, in conjunction with the Ministry of Finance
5. Establishment of internal policies and procedures.
6. Establishment of The National Accreditation for Health Care Facilities
7. Issuance of Hospital categorization and accreditation regulations.
8. Issuance of Professional Licensing Regulations.
9. Establishment of electronic drug registration submissions (eCDT)
10. Implementation of the on line customs release for drugs and medical devices.
11. Issuance of regulatory technical standards for alternative medicine centers.
12. Establishment of a committee for accountability of private healthcare facilities by ministerial decree, that is responsible for investigating



- violations of private health care facilities and taking disciplinary action.
13. Development of four disciplinary committees that are responsible for investigating violations by healthcare professionals.
  14. Development of internal policies and procedures for the disciplinary committees.
  15. Development of internal licensure policy.
  16. Implementation of a National Continuing Professional Development Program and paving the way to link this program with the process of license renewal for health professionals.
  17. Development of regulatory standards for licensing clinical trials.
  18. Development of guidelines for classification of pharmaceuticals and health food.
  19. Updating the medical device policy and procedure.
  20. Improvement of drug registration procedures.

Our achievements in the past year have been made possible through the commitment and professionalism of the dedicated staff at NHRA, all of whom work to improve, promote and protect the health of our people in the Kingdom of Bahrain.

Reflecting on last year's achievements, I am encouraged by the progress we have made in improving the healthcare environment in Bahrain.

This year we have reaffirmed our commitment to working across the health sector to make the most positive impact on people's lives. The implementation of The National Accreditation for Health Care Facilities will reflect healthcare facilities commitment to improving healthcare across the care continuum and prioritizing safe care to the people of Bahrain.

I look forward to seeing the impacts of these initiatives on the health and care of many people in Bahrain.

This annual report will demonstrate, key performance indicators achieved and will highlight the tasks performed by NHRA for the year 2016.



Our Vision is “to ensure **safe and high quality in the delivery of health services**”

***Dr Mariam Al- Jalahma***  
**CEO**



## 2016 Regulations

Supreme Council of Health issued the 14 new regulations for the year 2016:

Decisions
Decision No. (7) For 2016 regarding standards for assessing the health services quality and models of performance measurement indicators for the private health institutions
Decision No. (8) For 2016 regulating Over The Counter medications
Decision No. (9) For 2016 Pharmaceuticals products classifications
Decision No. (10) For 2016 Regulating Disciplinary Committees.
Decision No. (11) For 2016 Regulating licensure exams.
Decision No. (12) For 2016 Regulating drug registrations.
Decision No. (15) For 2016 Regulating accountability committee in NHRA
Decision No. (16) For 2016 Regarding Accountability Committee in NHRA
Decision No. (17) For 2016 Determination of license fees and service categories done by the NHRA to Healthcare professionals and the Profession of Pharmacy
Decision No. (20) For 2016 regarding identifying fee categories for private health institutions.
Decision No. (24) For 2016 regarding list of allied health professions.
Decision No. (26) For 2016 regarding evaluation and accreditation of private hospitals.
Decision No.(33) Regulating the practice of complementary and alternative medicine professional technical requirements for the licensing of private facilities
Decision No.(40) regulating professional licensing

These regulations have had a significant impact on the performance of NHRA in 2016.



## Department of Professional Licensing

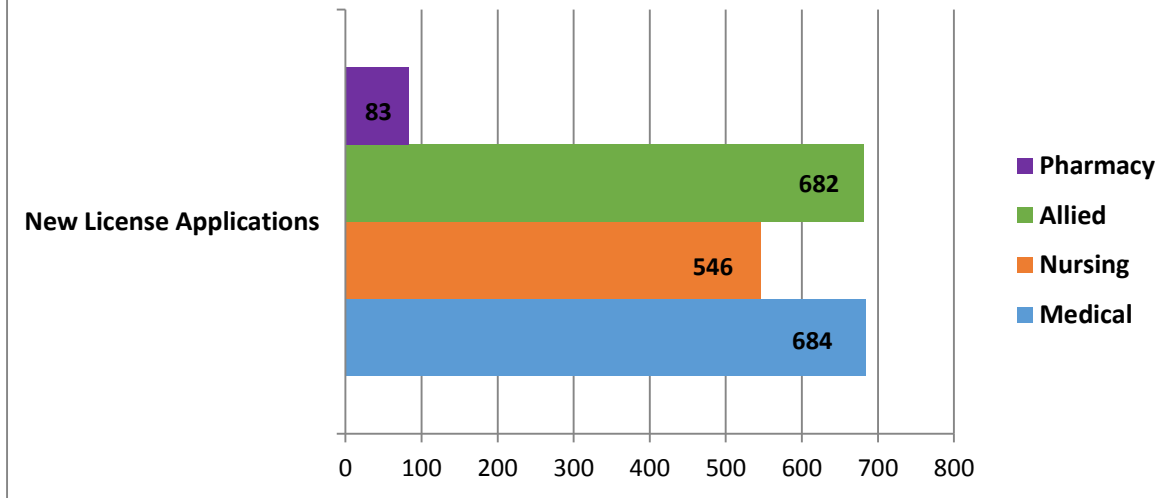


**Professional Licensing Team**

The Department of Health Professional Regulations manages the registration and renewal processes for health practitioners in the Kingdom of Bahrain. Its function is to ensure that standards of education, training and assessment of healthcare professionals promote and protect the health of the people of Bahrain. Credentials of professionals that enter the healthcare field are thoroughly assessed with respect to their knowledge, clinical skills and professional attributes that are necessary to practice here. Moreover, recognition of new medical specialties are evaluated and reviewed for the evidence based significance and safety profiles.

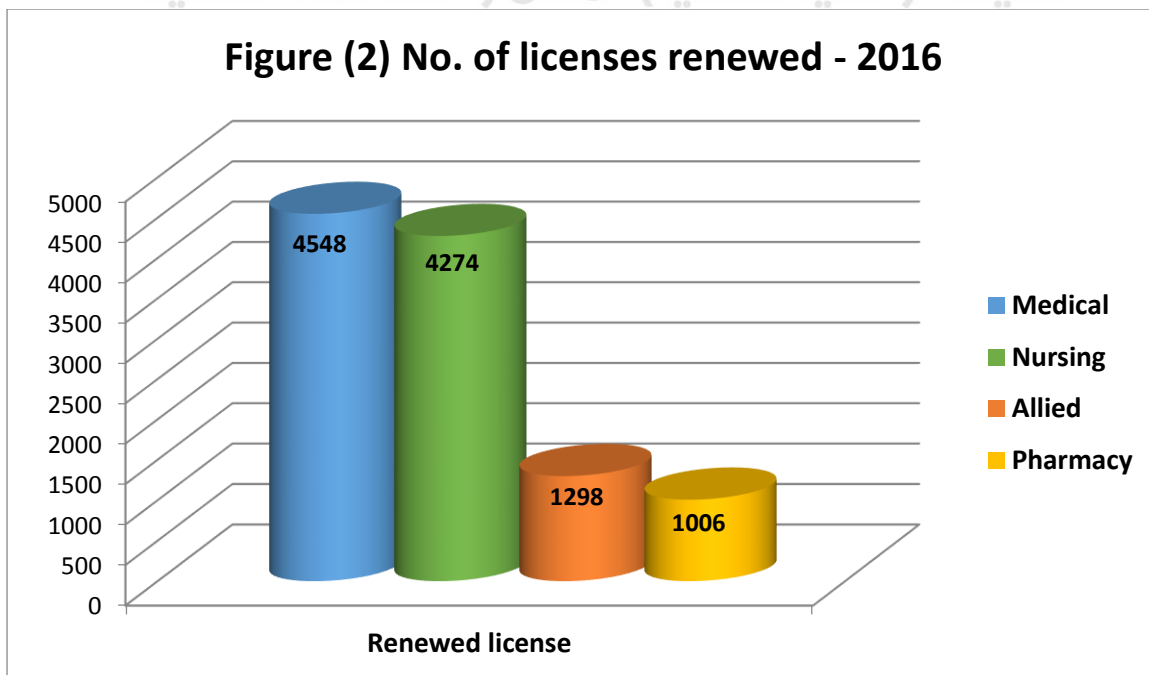
In 2016 the department of professional regulation received a total of (1,995) new license applications; renewed (11,126) licenses for professionals, and conducted a total of (7) licensure examinations. The total number of licensed healthcare professionals registered at NHRA in the Kingdom of Bahrain is 95,320. *Figure (1) demonstrates the distribution of new license applications by profession for 2016.*

**Figure (1) Distribution of New License Applications  
By Profession - 2016**



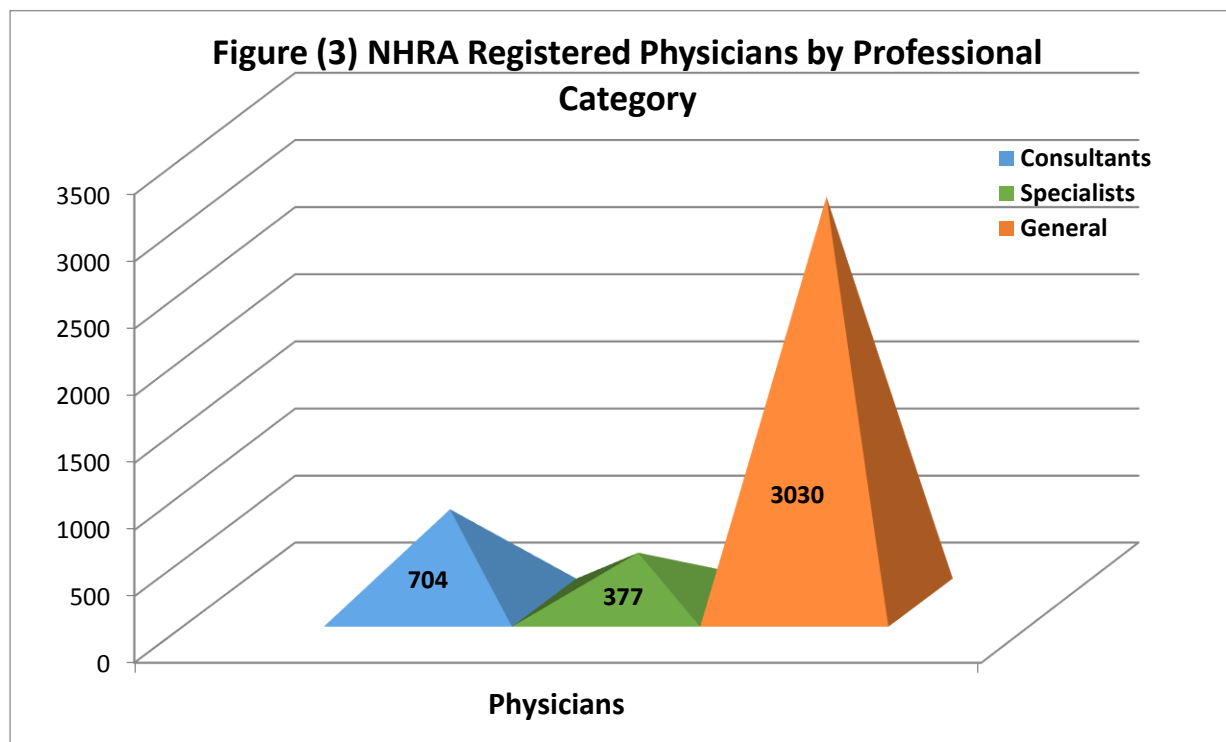
At renewal of licenses, all licensed medical practitioners are required to participate regularly in continuing professional development (CPD) that is relevant to their scope of practice. This involves maintaining, developing, updating and enhancing their knowledge, skills and performance to ensure they deliver appropriate and safe care. This process of continuous professional development is a vital component to fulfil NHRA's strategic priorities to provide safe and trusted health services. *Figure (2) demonstrates the distribution of licenses that were renewed in 2016 by profession.*

**Figure (2) No. of licenses renewed - 2016**

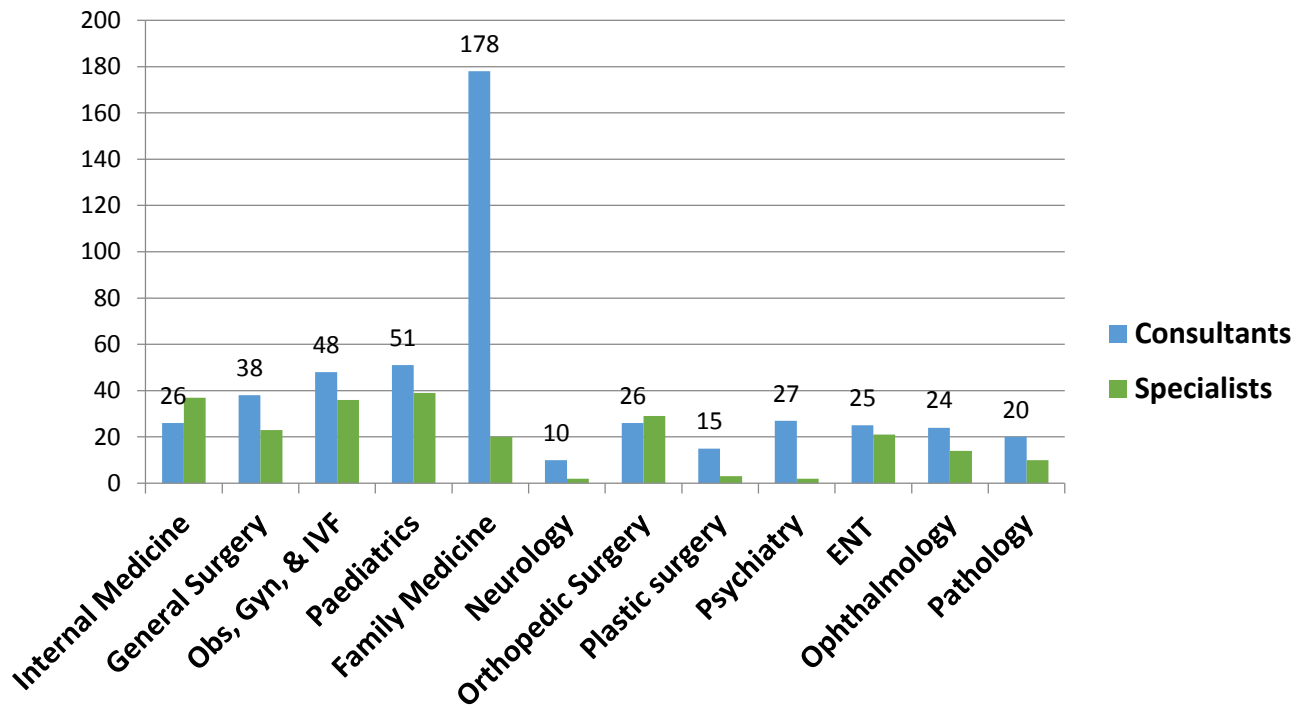


For the year 2016 the Department of Health Professional Regulations at NHRA reviewed its processes for licensing of healthcare professionals. The outcome of this review process highlighted the delays involved in the verification process and issuing of licenses. These delays were addressed and rectified which resulted in a more efficient review process without a compromise in quality and safety due diligence. *Figures (3) to (14) demonstrate licensing statistics of the department.*

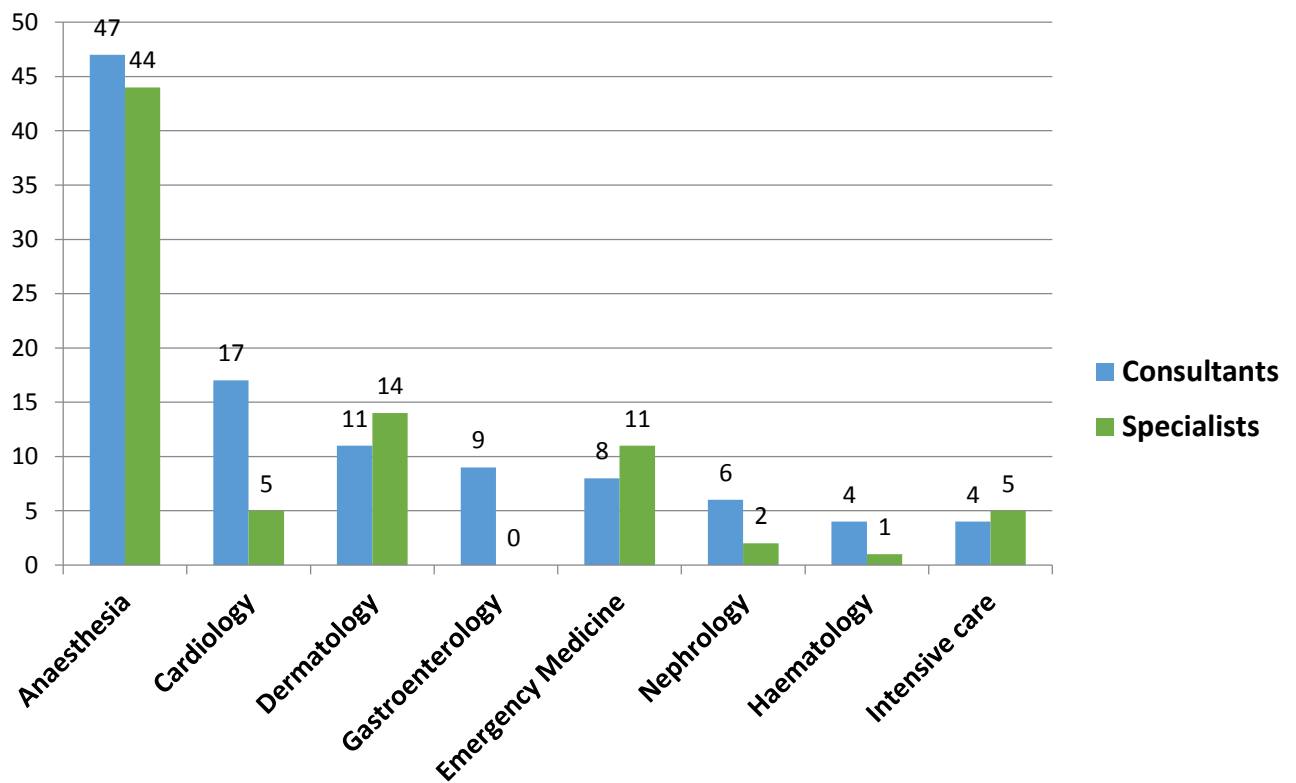
### Physician Licensure



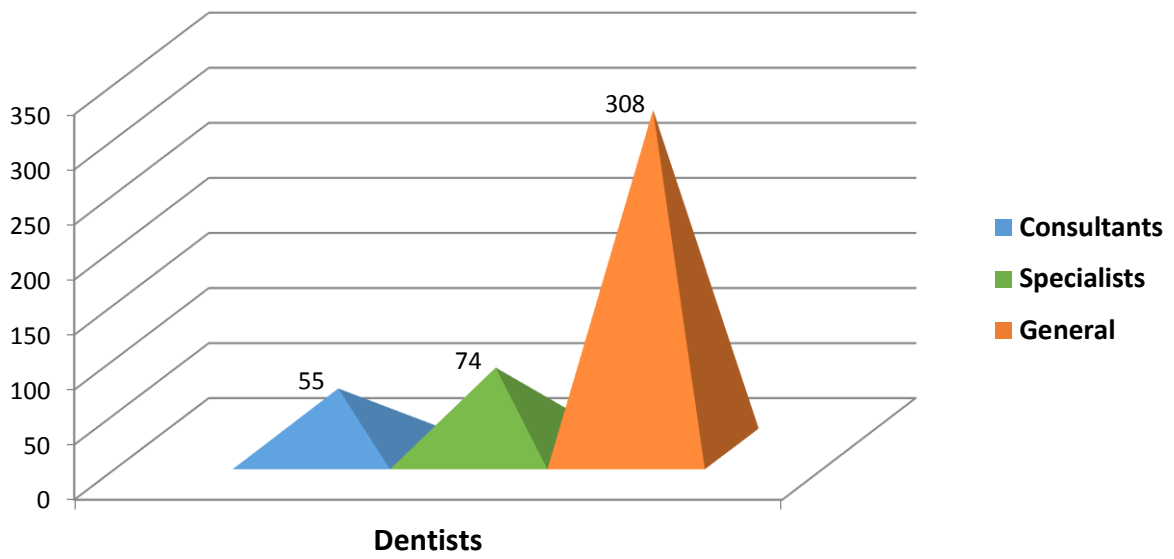
**Figure (4) NHRA Registered Physicians Per Specialty 2016**



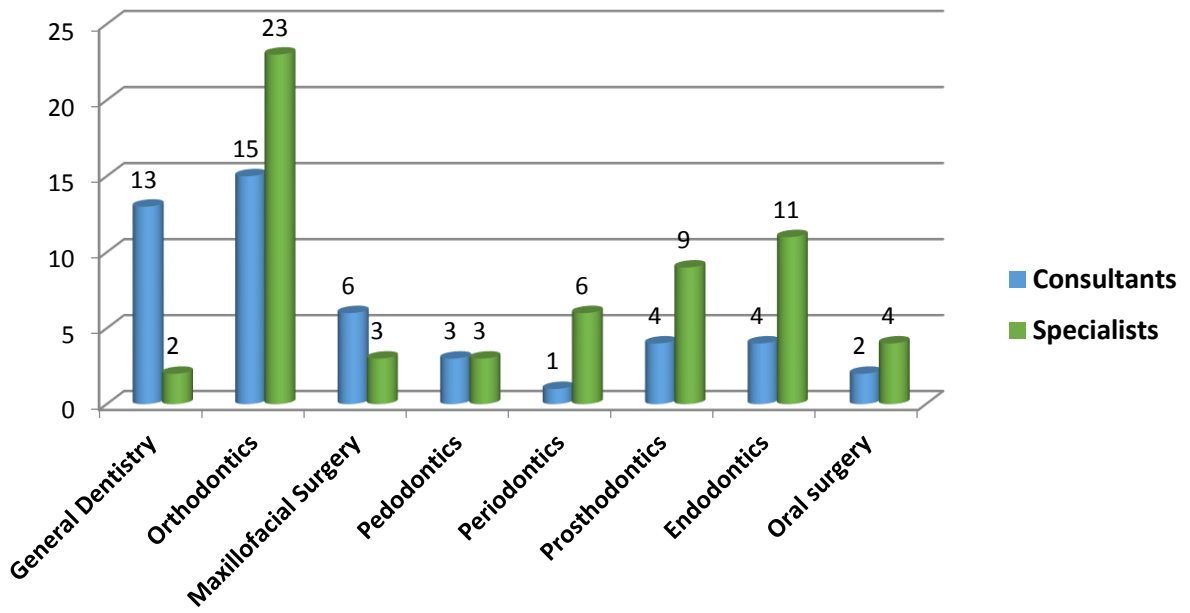
**Figure (5) NHRA Registered Physicians Per Specialty 2016**



**Figure (6) NHRA Registered Dentists by Professional Category**



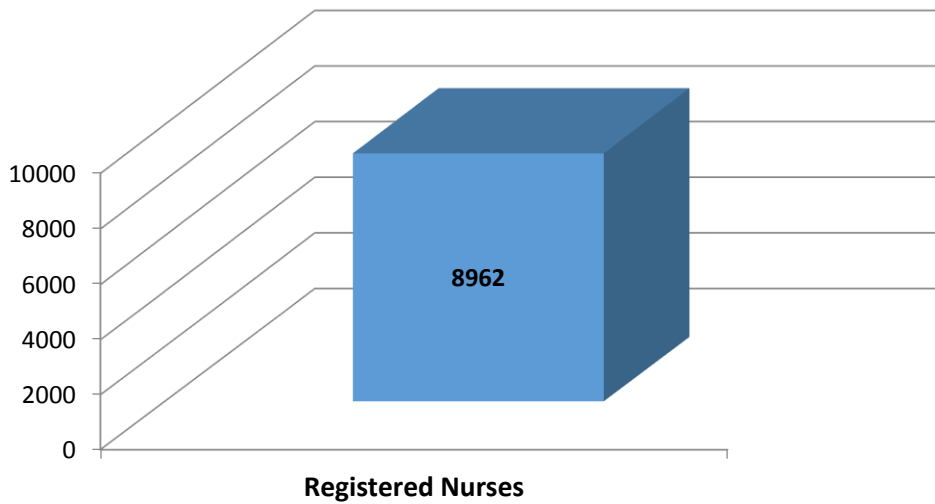
**Figure (7) NHRA Registered Dentists per Specialty 2016**



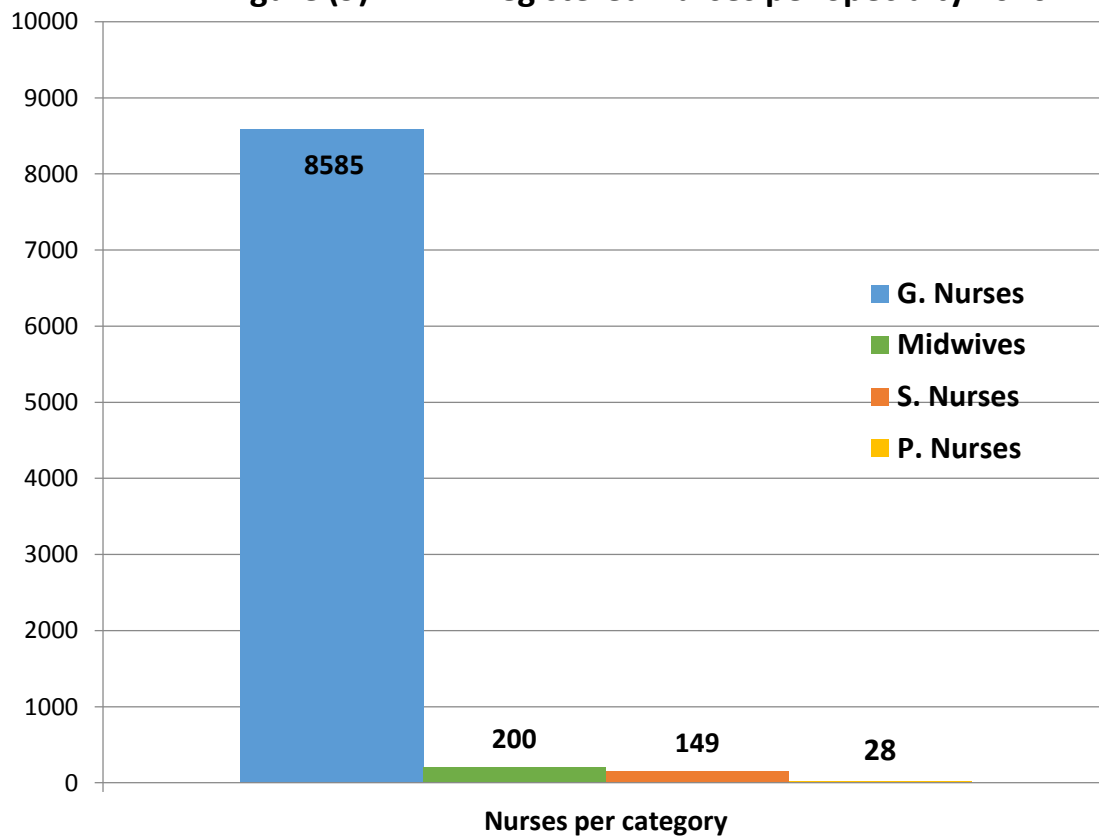


## Nurses Licensure

**Figure (8) Total No. of NHRA Registered Nurses 2016**

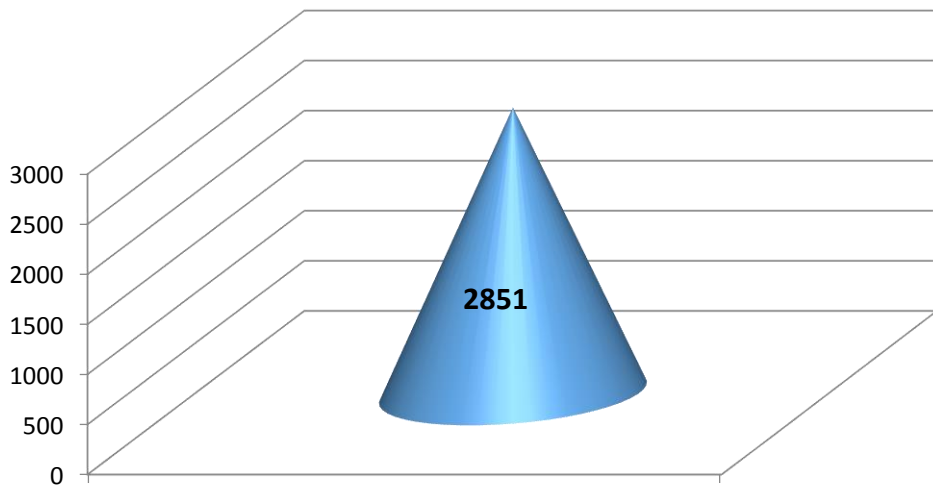


**Figure (9) NHRA Registered Nurses per Specialty 2016**

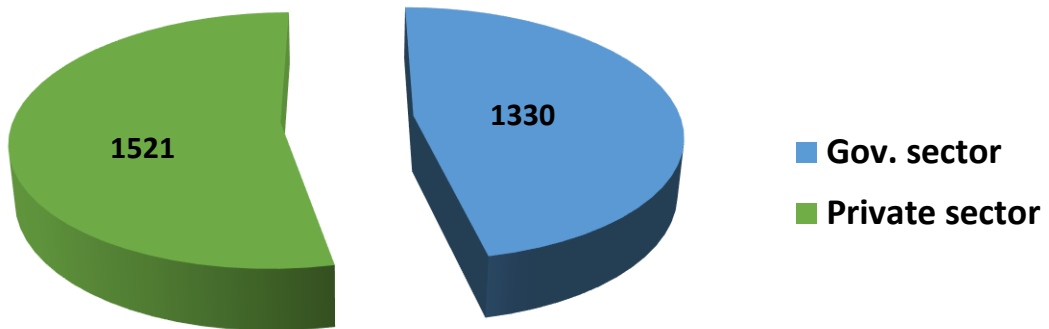


## Allied Health Professionals Licensure

**Figure (10) NHRA Registered Allied Health Professionals**

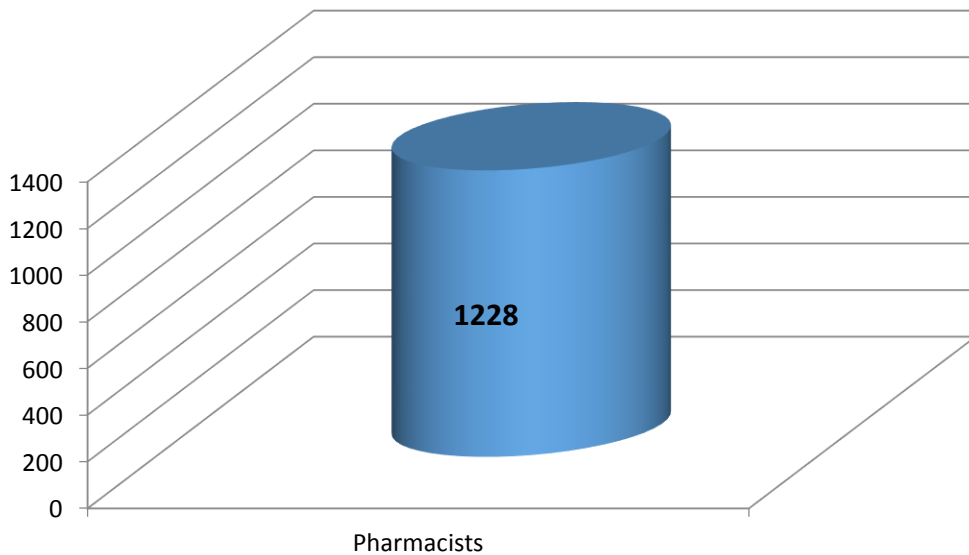


**Figure (11) Distribution of NHRA Registered Allied Health Professionals - Private Vs Government Sector**

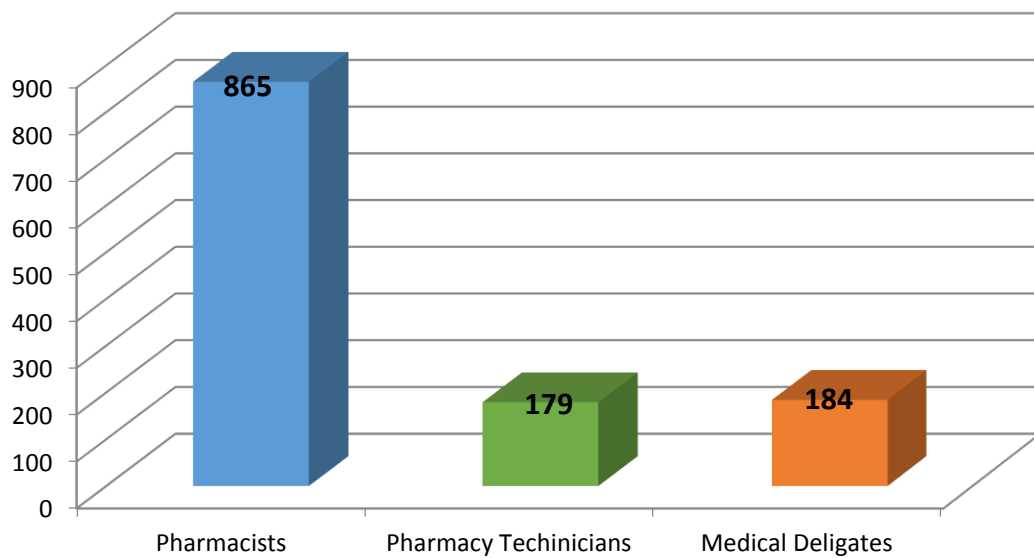


## Pharmacist Licensing

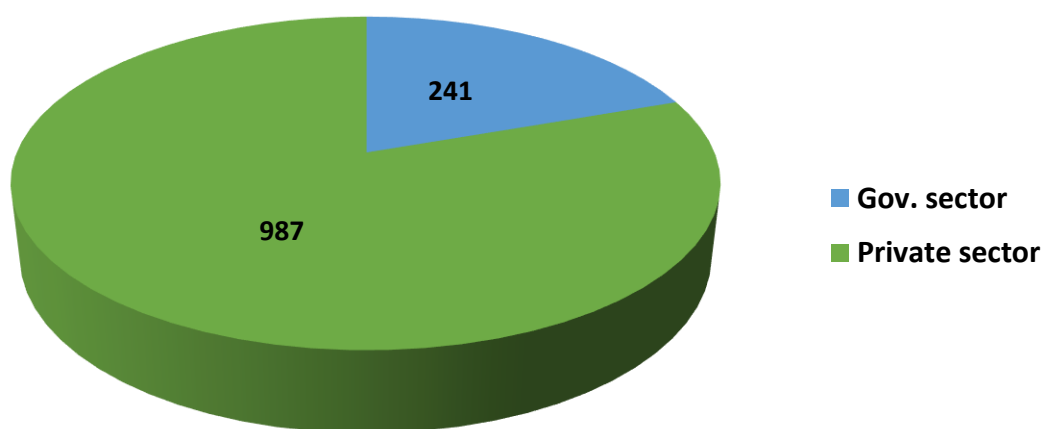
**Figure (12) Total No. of NHRA Registered Pharmacists**



**Figure (13) NHRA Registered Pharmacists Per Specialty**



**Figure (14) Distribution of NHRA Registered Pharmacists - Private Vs Government Sector**

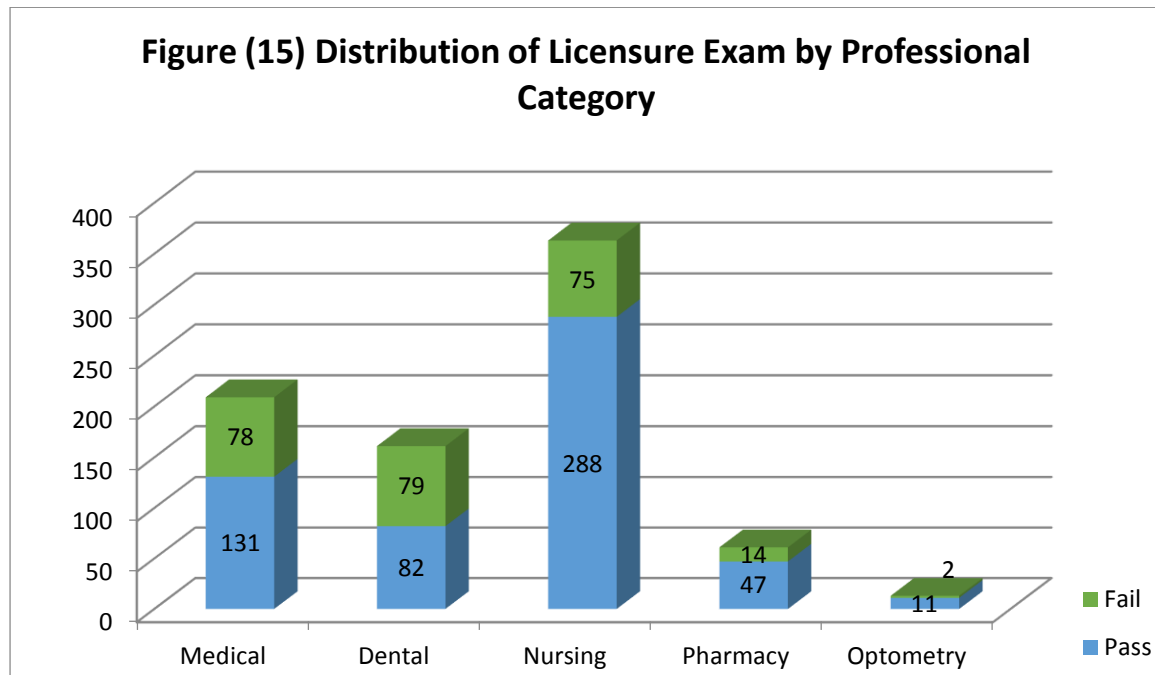


### **Going Forward**

The future directions of the Department of Health Professional Regulations in collaboration with the Department of Health Care Facility Licensing are initiatives to strengthen its data intelligence of licensed healthcare workers by developing a forecasting model that projects the unmet needs in the healthcare sector for Bahrain. The aim of this model will be to estimate the future supply of Bahrain's medical, nursing, pharmacist and allied health workforce. These workforce projections will help in identifying how NHRA can support a sustainable health workforce that is able to meet the future demand for health care.

## Licensure Exams

In order to facilitate licensing procedures for new professionals, NHRA has increased the number of annual exams for each profession. The dates of the examinations were available on the NHRA website site at the start of 2016.



## **Health Care Facility Licensing**



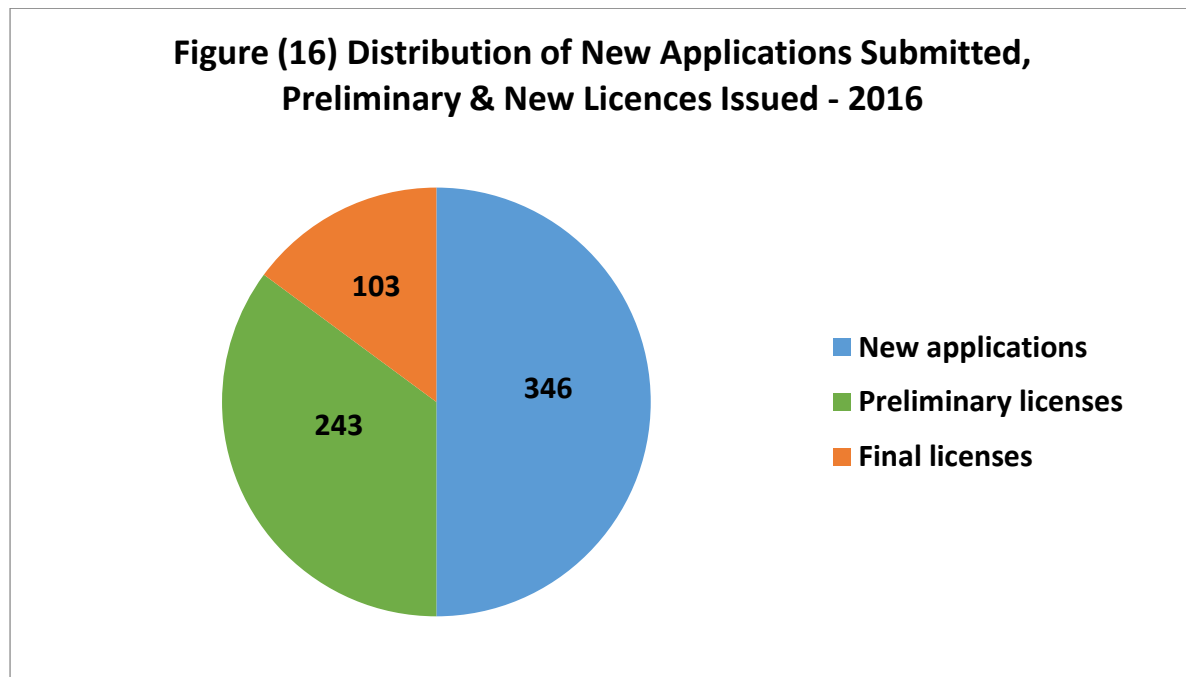
**Health Care Facility Licensing Team**

The Healthcare Facilities Licensing Department's primary function is to receive and register requests for licensing and operation of health care facilities, this also includes any amendments of the activities of licensed health facilities, approval on partial or total closure of the facility.

The procedure for issuing licenses has become more streamlined in the past year mainly due to the introduction of the SIJILAT system from the Ministry of Trade and Commerce. Applicants can upload the required documents which can now be reviewed by the healthcare facilities licensing department. Upon completion of this review a preliminary license is issued. Subsequent to this, all remaining documents should be submitted by the applicants and a site inspection will be scheduled usually in a 2 week timeframe. A final license will be issued after completion and verification of the above process.

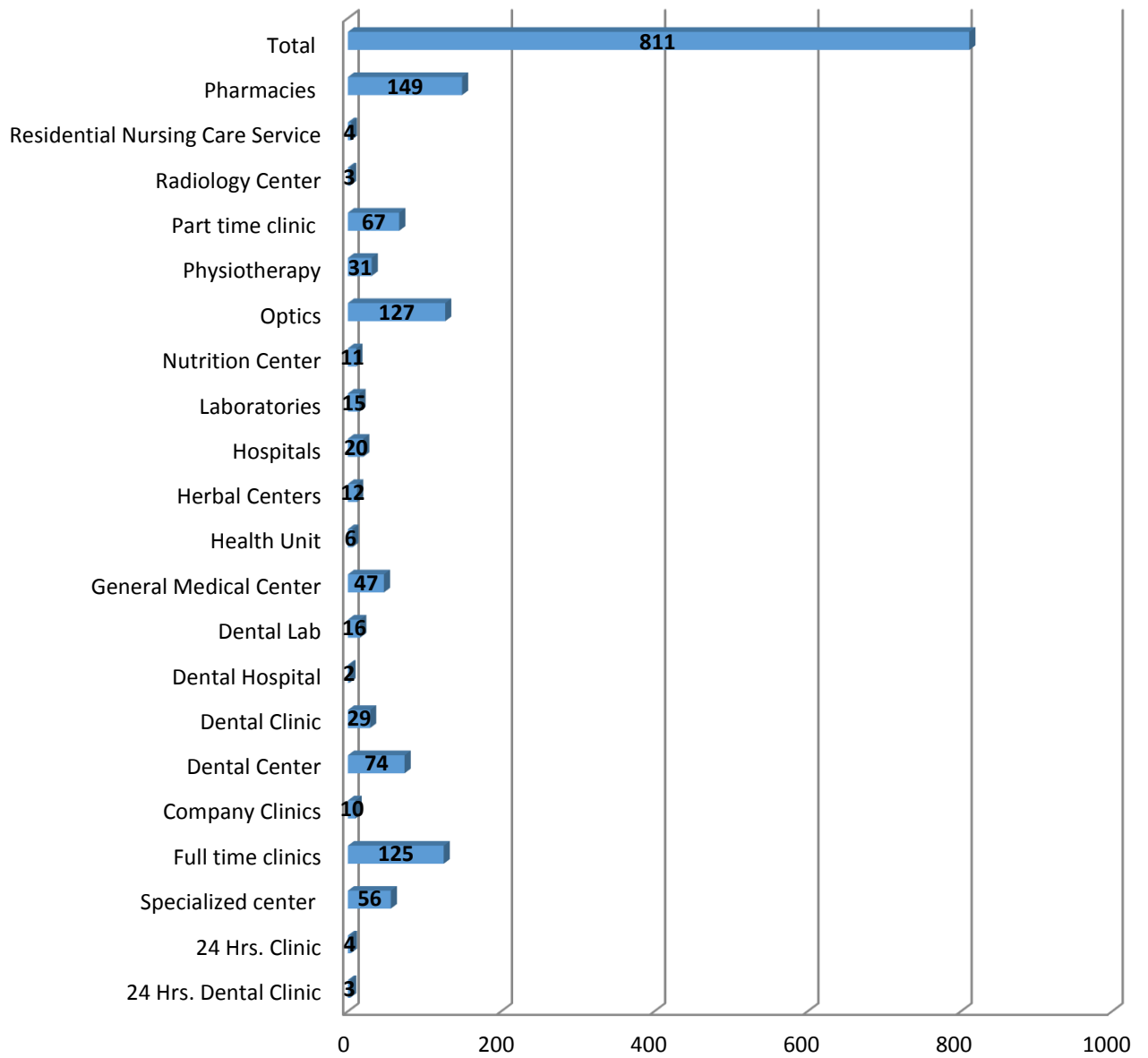


In 2016, the Department of Health Care Facilities Licensing, received **346** new applications, issued **243** preliminary licenses, and **103** final licenses, *as shown in Figure (16).*

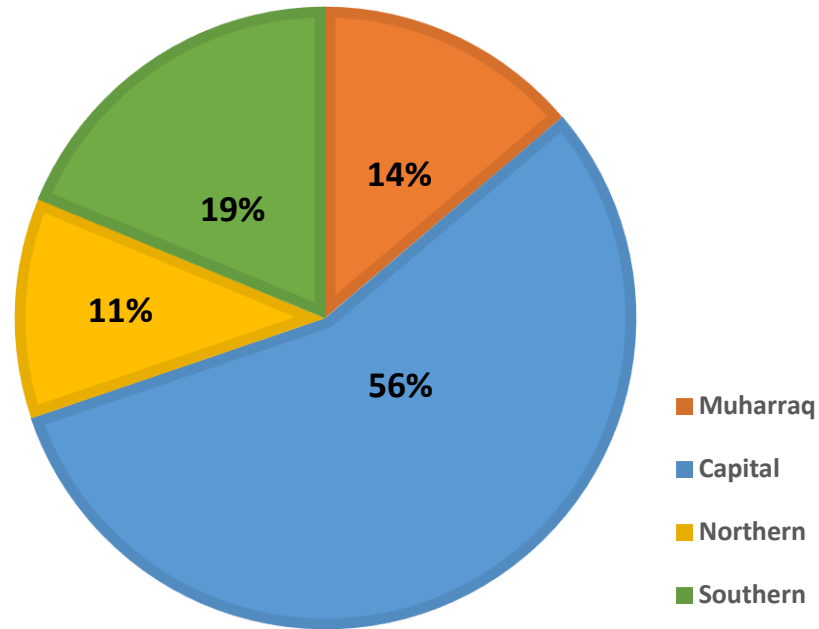


The total number of facilities registered in NHRA to date is **811**, these include **381** medical care facilities, **124** dental health care facilities, **149** pharmacies, **127** optic shops, **15** laboratories, **3** radiology centers and **12** alternative medicine centers. *Figures (17) to (19) show the classification and geographic distribution of healthcare facilities in the Kingdom of Bahrain.*

**Figure (17) Classification of Facilities Registered With NHRA - 2016**



**Figure (18) Geaographic Distribution of Healthcare Facilities in the Kingdom of Bahrain**

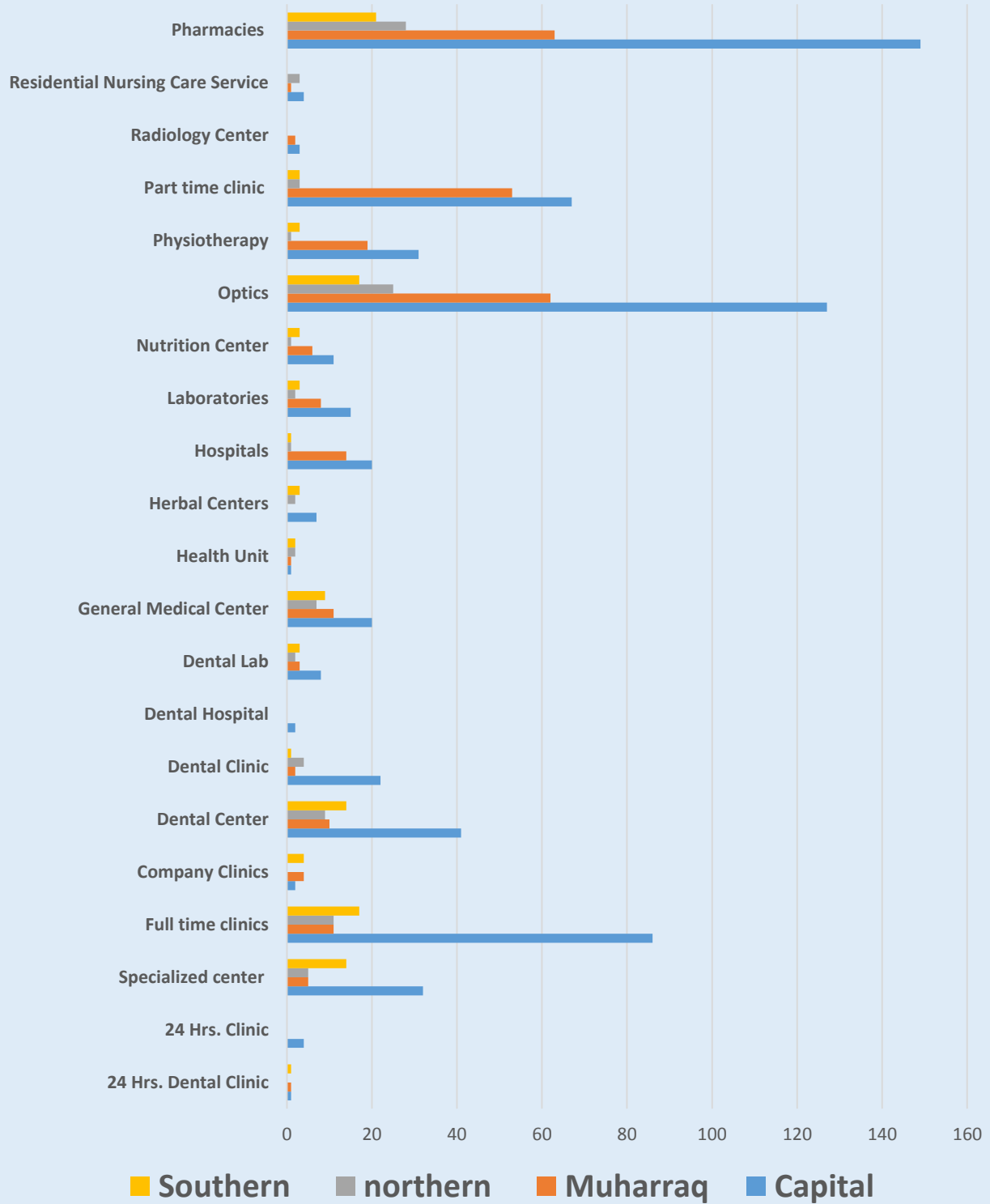


BAHRAIN



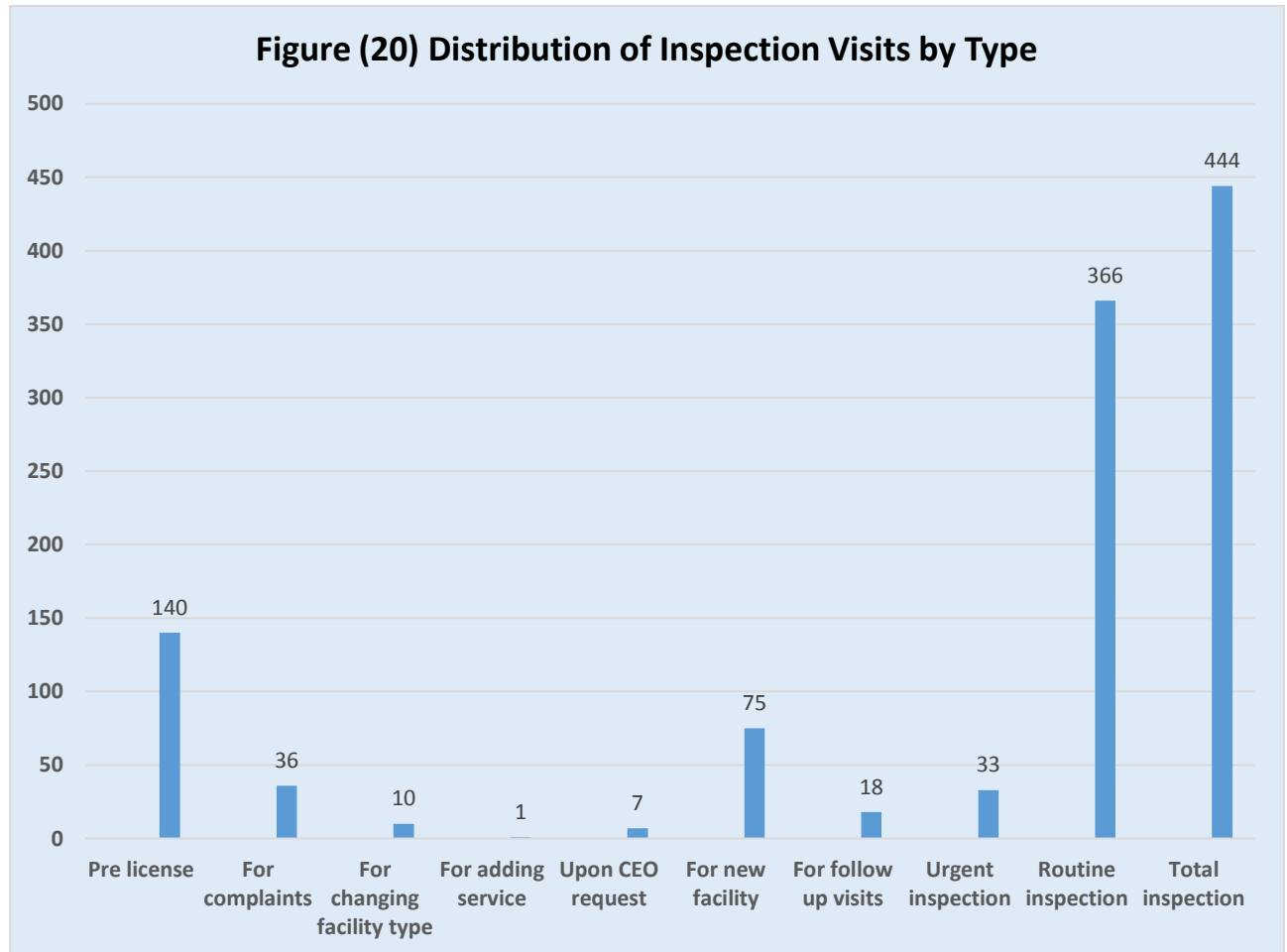
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**Figure (19) Geographic Distribution by Governorates of the Types of Health Care Facilities Available in the Kingdom of Bahrain**

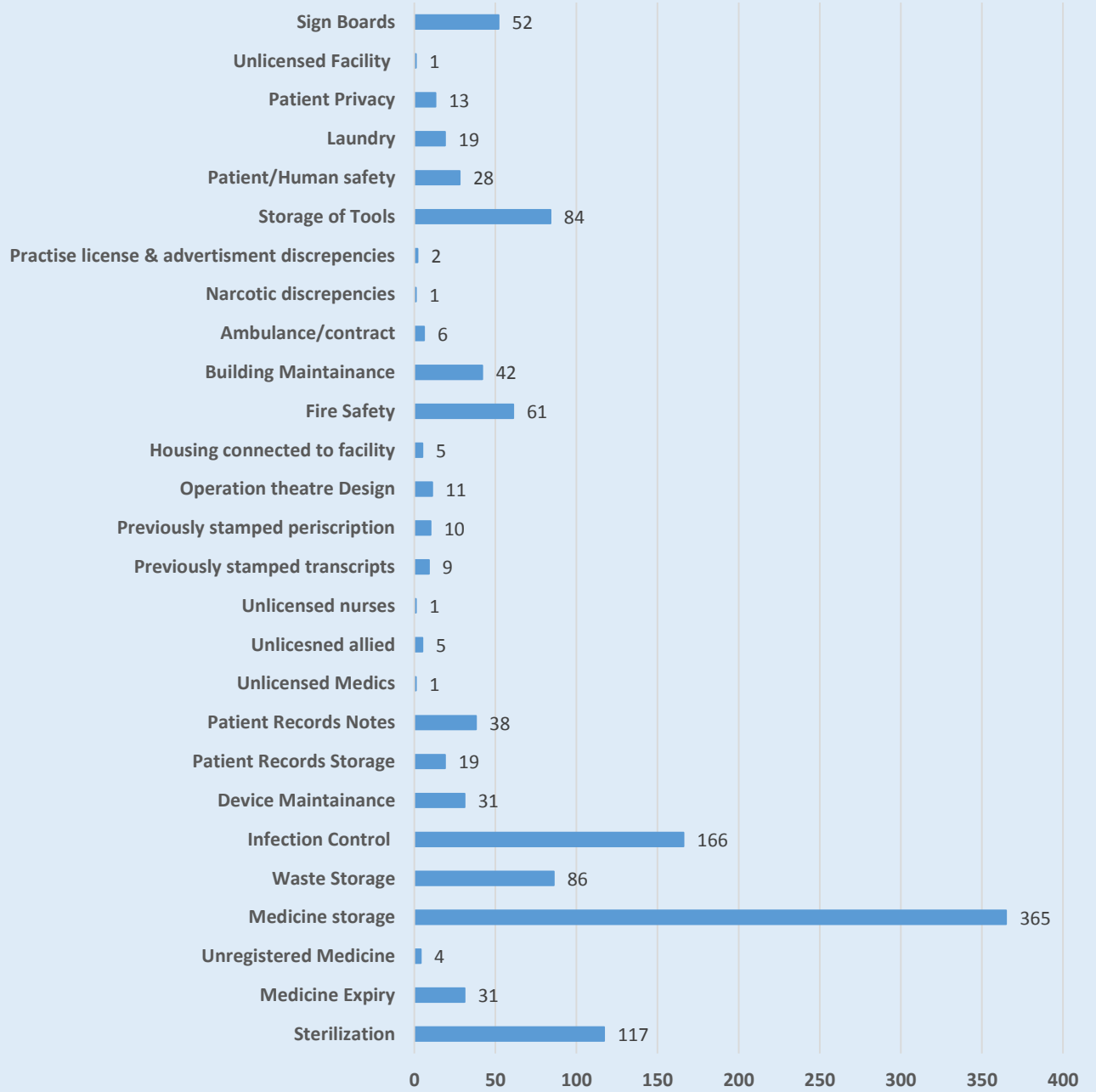


## Inspection Activities

In 2016 NHRA inspectors conducted a total of 444 site inspections to ensure compliance to NHRA standards and regulations. Figures (20) and (21) show the breakdown of inspections conducted by the basis on which they were carried out and the types of violations that were identified.



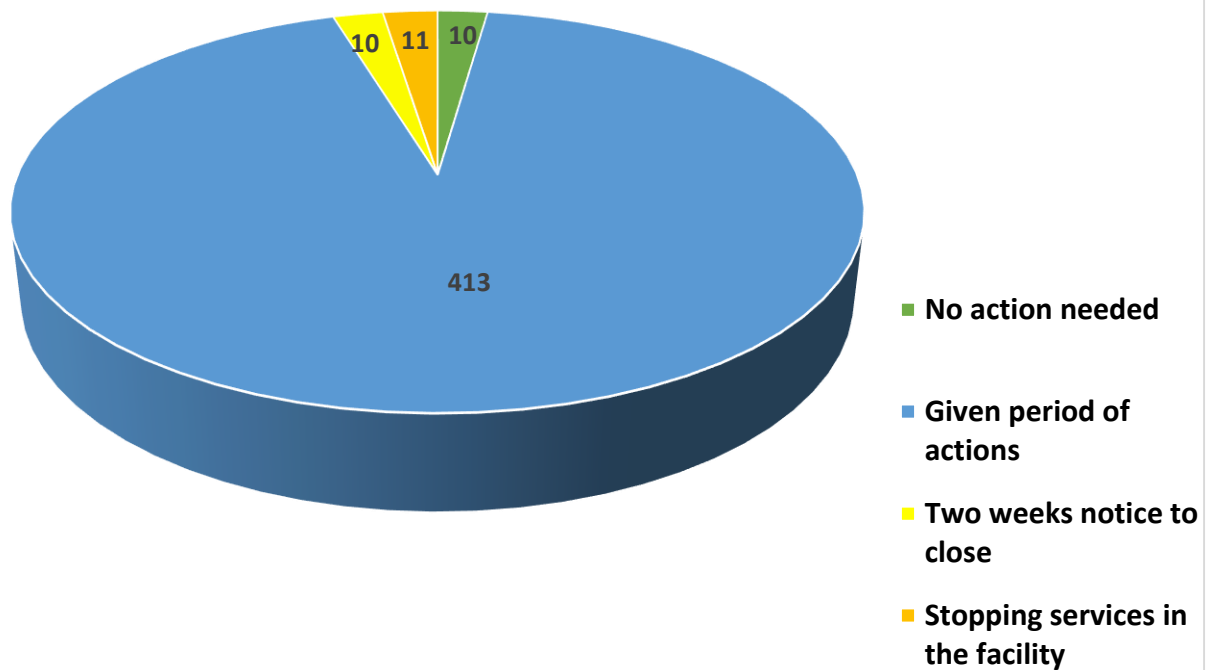
**Figure (21) Types Of Violations Identified During Inspection Visits**





As a result of the inspections both major and minor violations were identified such as medication storage, infection control, waste disposal, inadequate sterilization techniques etc. *Figure (22) shows the actions taken by NHRA against the violating facilities.*

**Figure (22) Action Taken by NHRA Against Violating Facilities**



## Pharmacy Licensing



In 2016, NHRA issued 49 licenses for new pharmacies out of which 9 were for hospital pharmacies. A total of 70 licenses were renewed for existing pharmacies. The total number of pharmacies registered in the Kingdom of Bahrain is 188 (149 General Pharmacies and 39 Hospital Pharmacies). *Table 1 demonstrates the geographic distribution of pharmacies in the Kingdom of Bahrain.*

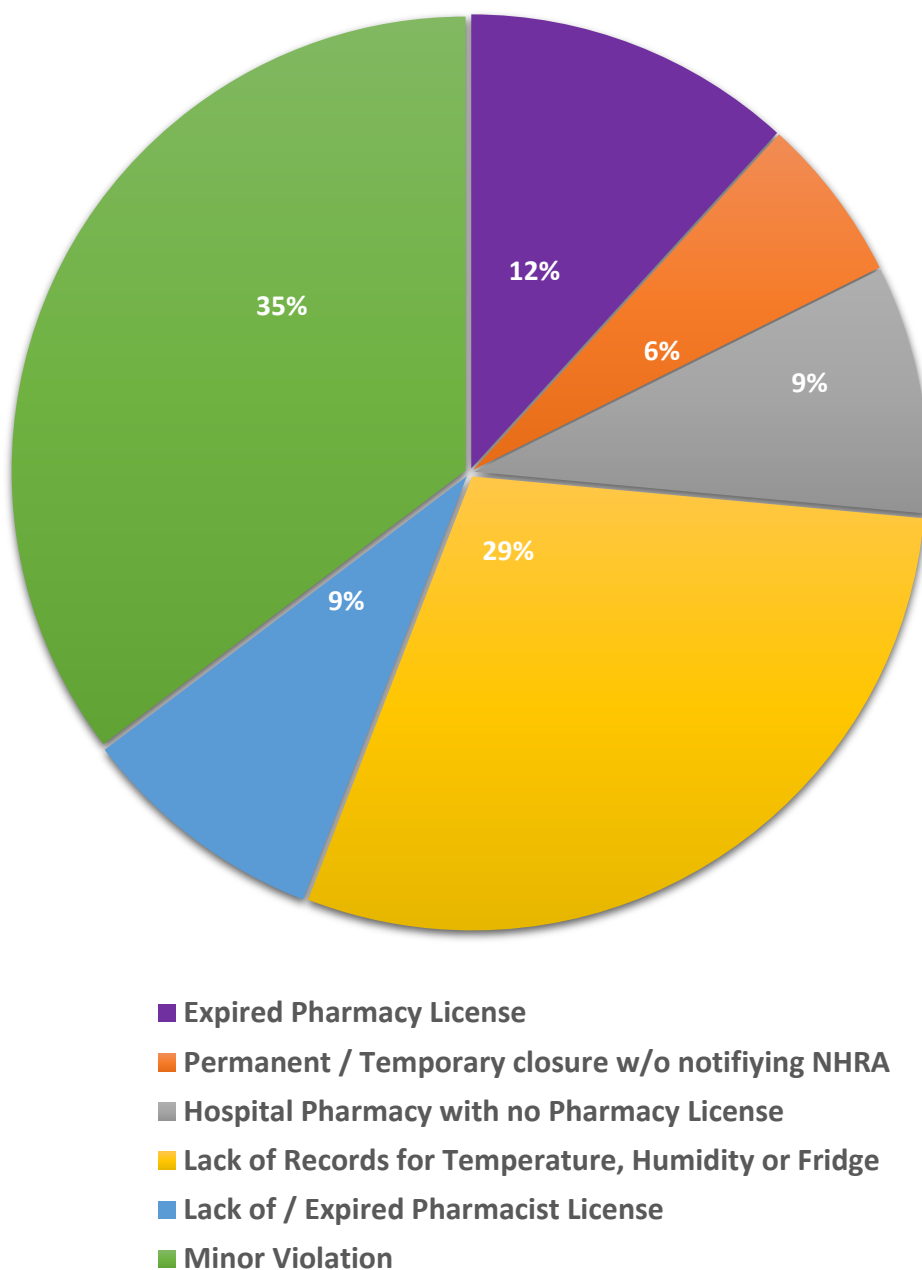
Governorate	Hospital Pharmacy	General Pharmacy
Muharraq	15%	19%
Manama	56%	42%
Northern	5%	14%
Southern	23%	25%

**Table (1): Geographic Distribution of NHRA Registered Pharmacies by Governorates**

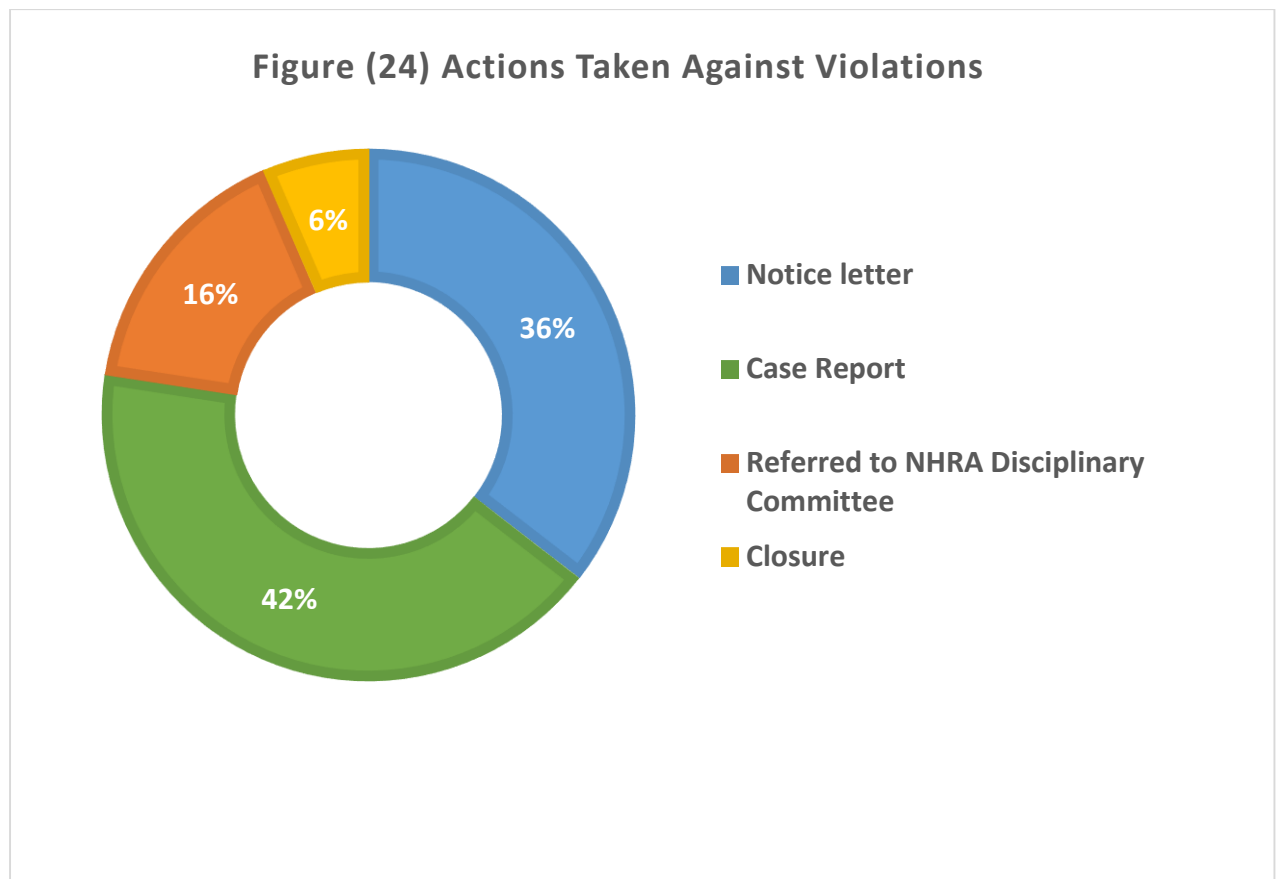
**Inspection Activities.**

A total of 327 inspection site visits were conducted to ensure compliance to NHRA pharmacy regulations and standards. Of those site visits, 34 violations such as; operating without a license / expired license or closure of pharmacies without notifying NHRA etc. were identified. *Figure (23) summarizes the types of violations identified.*

**Figure (23) Types of Violations Identified**



The actions taken against these violations are summarized in Figure (24):



## **Medical Devices Licensing**

Medical devices are all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability that does not achieve its action by pharmacological, immunological or metabolic means. NHRA was assigned by law (38) in 2009 to ensure all medical devices in healthcare facilities comply with international standards of quality and safety. NHRA, with the Ministry of Interior customs department located at all ports work in collaboration to ensure that all medical devices coming into the Kingdom of Bahrain are accounted for and are subject to review.

In 2016, NHRA established a classification criteria to be consistent with the global harmonized model (HS code) and fulfill NHRA's strategic priority to preserve patients' health rights and guarantee patient safety. The following international classification of medical devices was created:

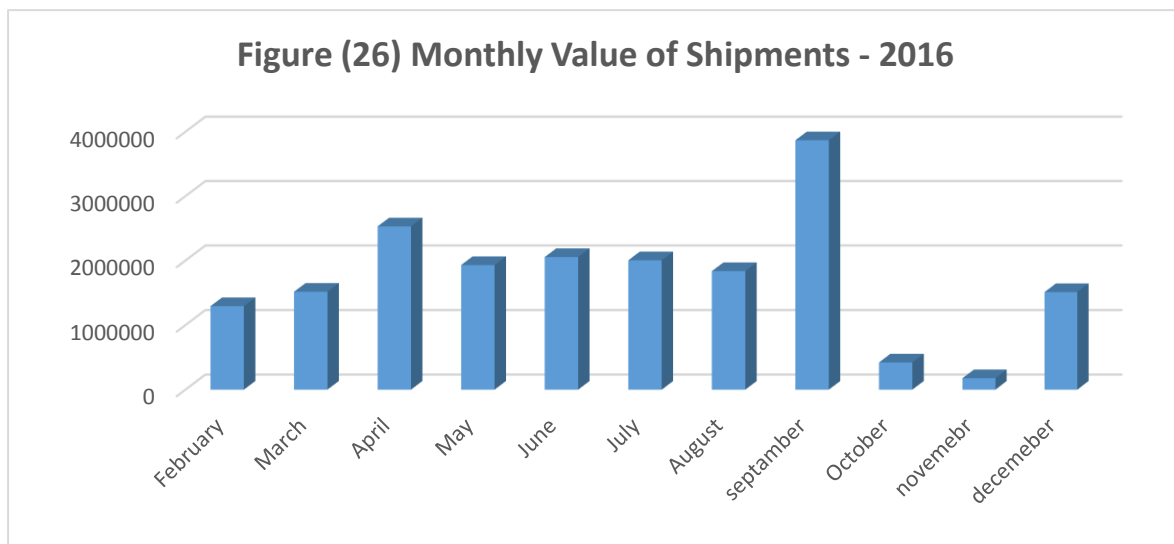
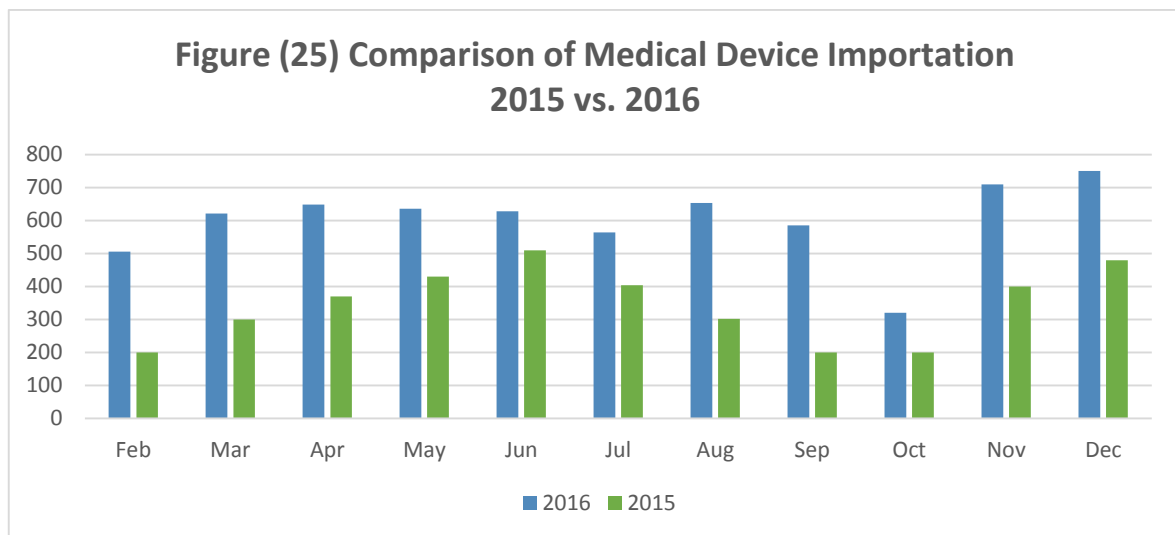
- ❖ I - Low Risk Medical Devices (such as Electronic Thermometer, Surgical light, surgical tube)
- ❖ II - Medium Risk Medical Devices (such as EEG, ECG, Endoscopes)
- ❖ III - High Risk Medical Devices (such as anesthesia machine, ventilator, heart - lung machine)

With the intention of establishing an effective monitoring system, in addition to complying with international current operative regulation recognized globally, NHRA is releasing permits only for Medium (II) and High Risk Medical Devices (III).

In 2016, NHRA also released new guidelines to regulate combined medical devices that include therapeutic and diagnostic products with combination drugs, devices, and/or biological products.

In the past year the licensing process has become more efficient mainly due to the adoption of the Customs electronic system (OFOOQ). This online system of submission has considerably cut down the time to facilitate the permits procedure and allows round the clock access to the application system which prevents delays to release shipments from ports. This system has considerably increased the number of shipments cleared.

A total of 7835 medical devices were imported in 2016 with a value of 19,145,181 Bahrain Dinars (value of Class II and III devices only). Almost 80 medical products were classified as a combined medical device. *Figure (25) and (26) below show the comparison between 2015 and 2016 medical device importation into the Kingdom of Bahrain and the monthly value of these shipments.*





On a global level NHRA has attained membership to the following international organizations:

- ❖ GSO (GCC Standardization Organization) medical device technical committee
- ❖ ISO/TC 210 "Quality management and corresponding general aspects for medical devices"
- ❖ Economic member in the AHWP (Asian Harmonization Working Party)



## Pharmaceuticals Licensing



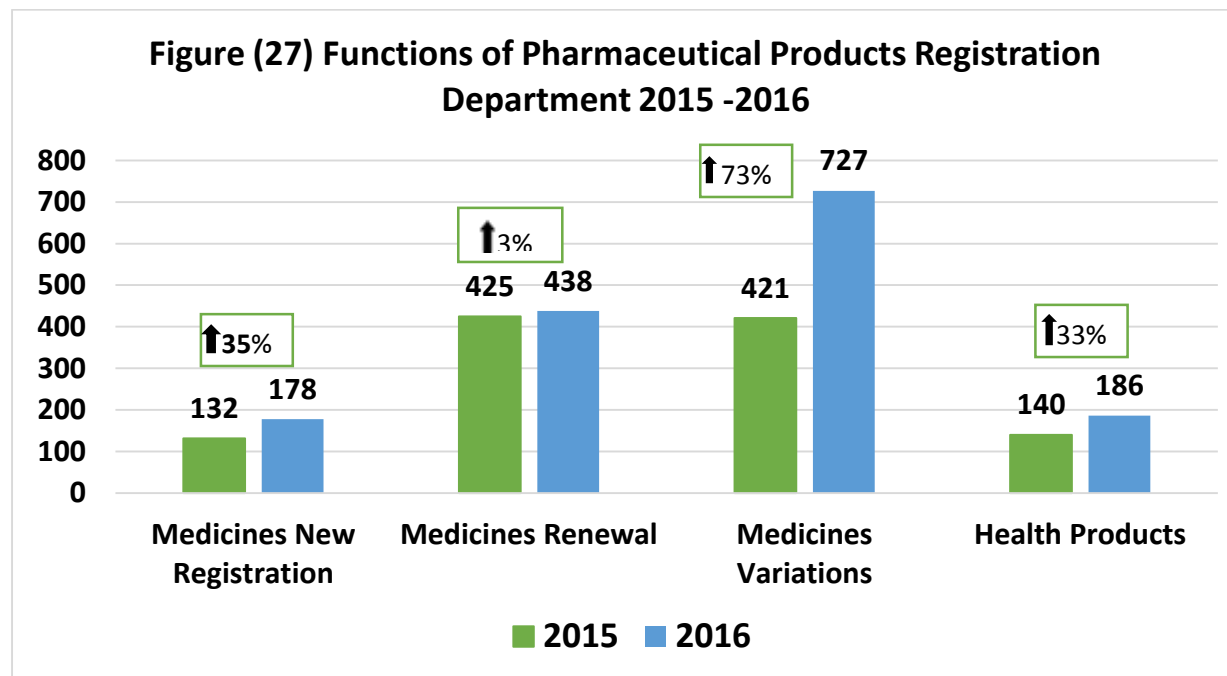
**Pharmaceutical Products Registration Team**

As an ongoing effort to ensure equitable access of quality medications to the people of Bahrain the Department of Pharmaceuticals Product Registration (PPR) has worked towards implementing systems to increase the review of medications systematically. Licenses for medicines are granted only when a product meets predefined standards of safety and quality and works for the purpose intended, while no product is free of risk but sound evidence underpins all NHRA decisions to ensure that these risks are minimized.

However, advances in technology often lead to the discovery of new medicines to help patients and therefore priority reviews are considered by the PPR department for medicinal products that are intended to treat life-threatening conditions and address unmet medical needs. This priority review process was put into effect in response to Supreme Health Councils regulation number (12) that regulates the licensing of non-registered medications and internationally registered ones outside the Kingdom facilitating timely access of medicines.

The implementation of these developments have contributed to a 35% increase in the registration of pharmaceuticals by the PPR department in the past year *see Figure (27)*.

Table (2) demonstrates additional functions of the PPR Department over the past two years.



Activity	Jan - Dec 2015	Jan - Dec 2016
Manufacturing Sites Registration	59	79
Products Classification	51	345
GCC & Local GMP Inspection	11	17
Parcels	2,616	2,216
Invoices Clearance	11,000	11,500
Pre-Approvals	2103	3,467
Non-registered Products Approvals	300	1,505

\*\*In 2016, 724 products were sent for destruction as they were found to be either expired, recalled or damaged.

**Table (2): Additional Functions of the Pharmaceutical Products Registration Department 2015 -2016.**

In addition to this, in 2016 the PPR department started the implementation of Electronic Common Technical Document (eCTD) - an interface for industry to agency transfer of regulatory information. eCTD submissions shorten the development timeline by simplifying drug life cycle management, it allows assessors to use computer-based tools such as searching, copying and pasting text, thus making the review process more efficient.

Following these achievements and in light of some recent high profile drug withdrawals, the future direction of regulating pharmaceuticals at NHRA is to develop and implement a Kingdom wide Pharmacovigilance Program in the coming future. This program will contribute to the assessment of adverse drug effects or any other possible drug-related problems, in addition to benefit, harm, effectiveness and risk of medicines, thereby encouraging their safe, rational and more effective (including cost-effective) use.

### **Pricing of medicines**

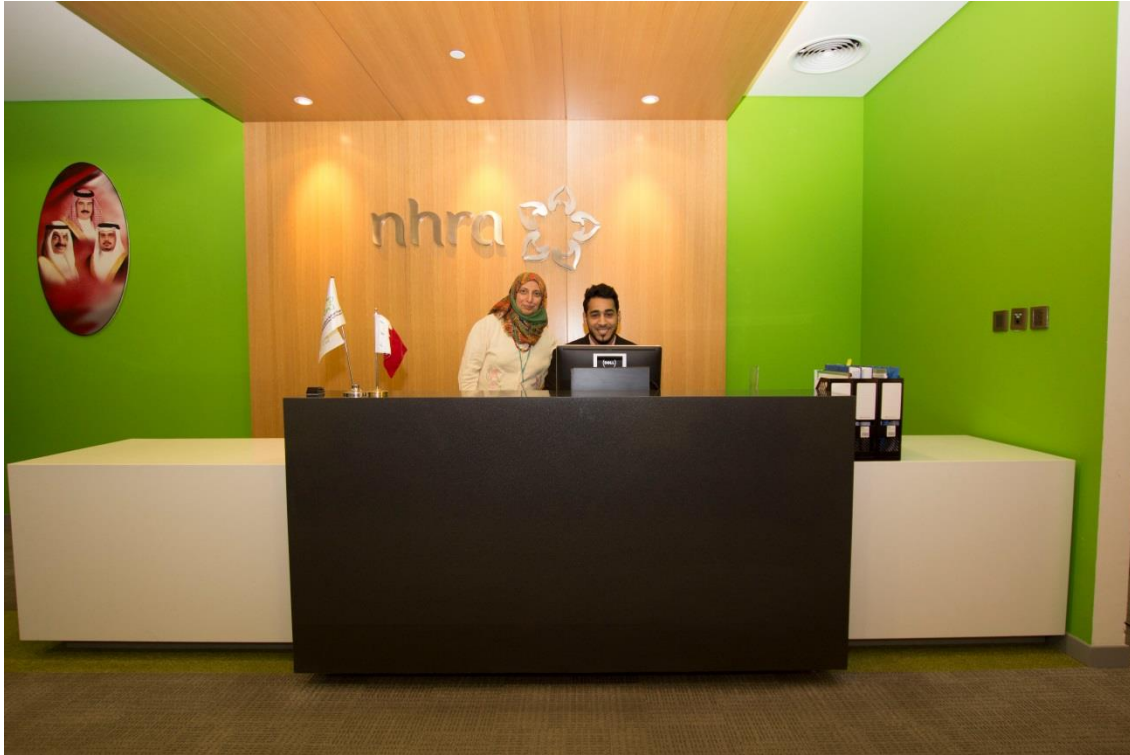
Equitable access to safe and high-quality essential medicines depends on affordable and fair pricing. The department has taken a deliberate approach to promote affordable and fair prices as this is central to meeting NHRA's strategic goals.

The PPR Department at NHRA has priced **516** medicines in total, of these **213** pharmaceutical products were assessed and priced by the PPR group. Furthermore, NHRA has contributed to the GCC unified pricing of **252** innovative drugs and **51** generic drugs (*see Table 3*) reaffirming NHRA's stance on providing affordable, safe medications to the people of Bahrain.

<b>Activity</b>	<b>Jan - Dec 2016</b>
GCC Unified Pricing	<b>Innovators: 252</b>

	<b>Generics: 51</b>
Medicines Assessed and Priced by NHRA	<b>213</b>

**Table (3): Overview of Pharmaceutical Products Pricing Activities**



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***Investigating Complaints with Medical Error Claims***



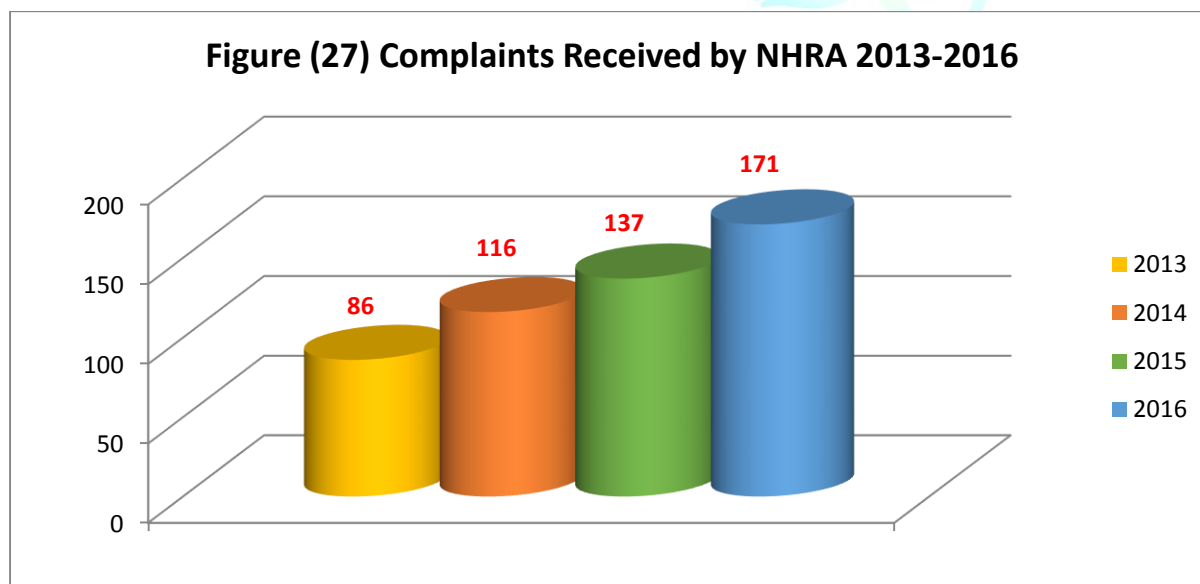
**Complaints Team**

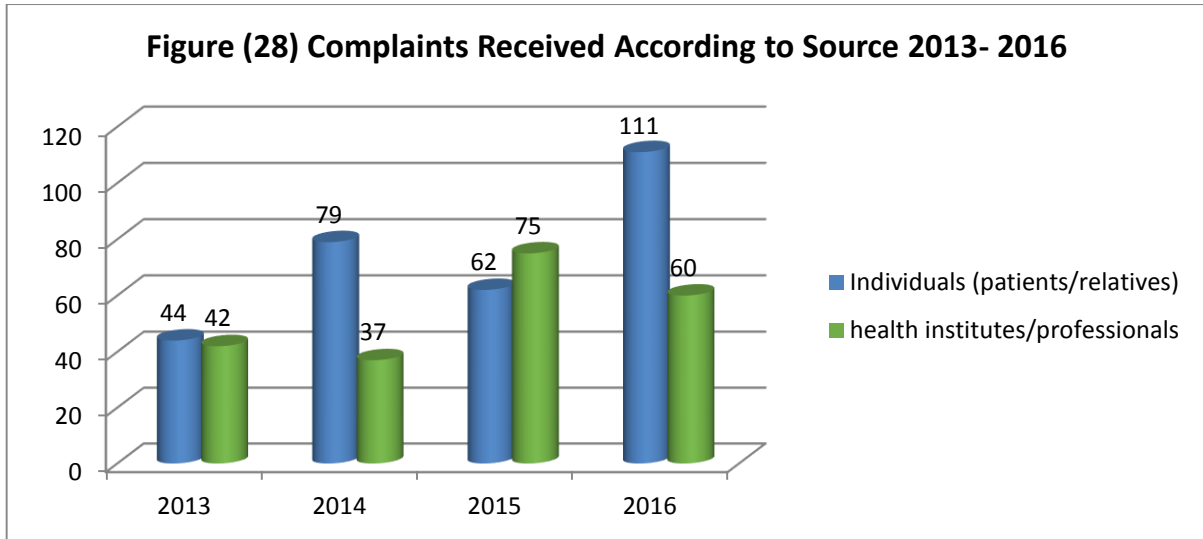
## Complaints

The NHRA complaints department receives complaints that vary greatly in their complexity. The vast majority of complaints are reviewed through a quality of care approach, with the objective of resolving misunderstandings, improving the quality of care and ensuring that patient safety is a top priority on all levels of care. These objectives serve as a basis to meet the strategic priorities of NHRA that are to *Provide Safe and Trusted Healthcare Services* and to *Preserve the rights of patients and prioritize patient safety*. A small minority of complaints involve matters that may give rise to concerns of unprofessional conduct or lack of skill and knowledge in the healthcare services provided.

In addition to this, the complaints department also receives incident reports from healthcare providers and centers to report any events that may have occurred whilst patients were in their care. This practice is being actively encouraged in order to increase the transparency of healthcare institutions and adopt a no blame culture for reporting.

*Figures (27) and (28) show the number of complaints received by NHRA and the source of the complaints from 2013 – 2016.*

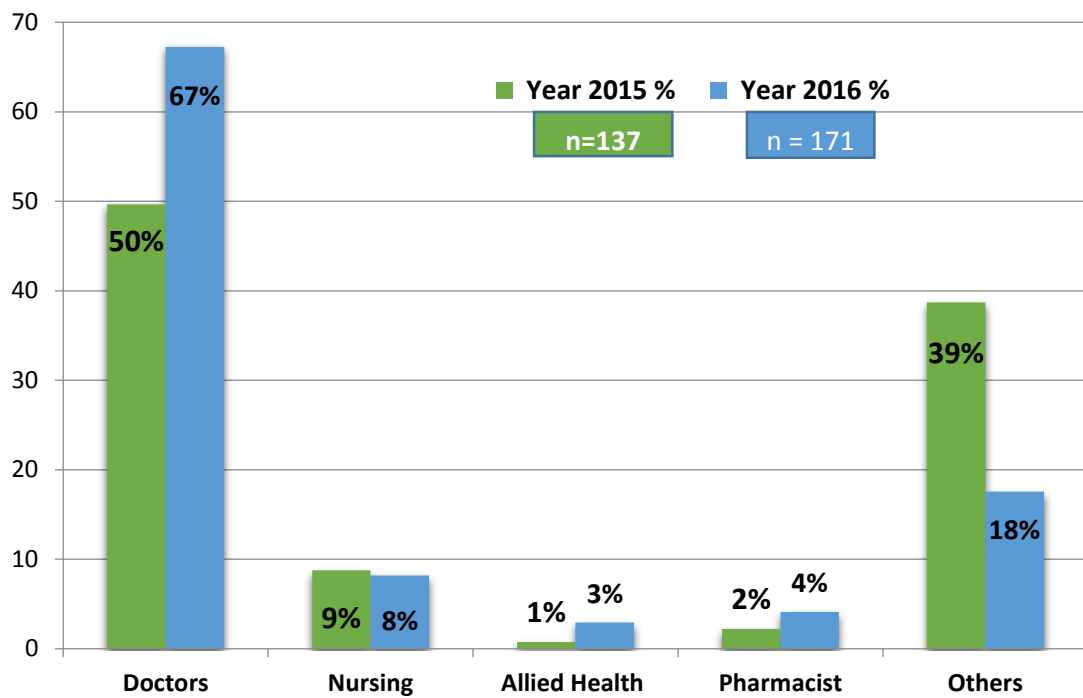




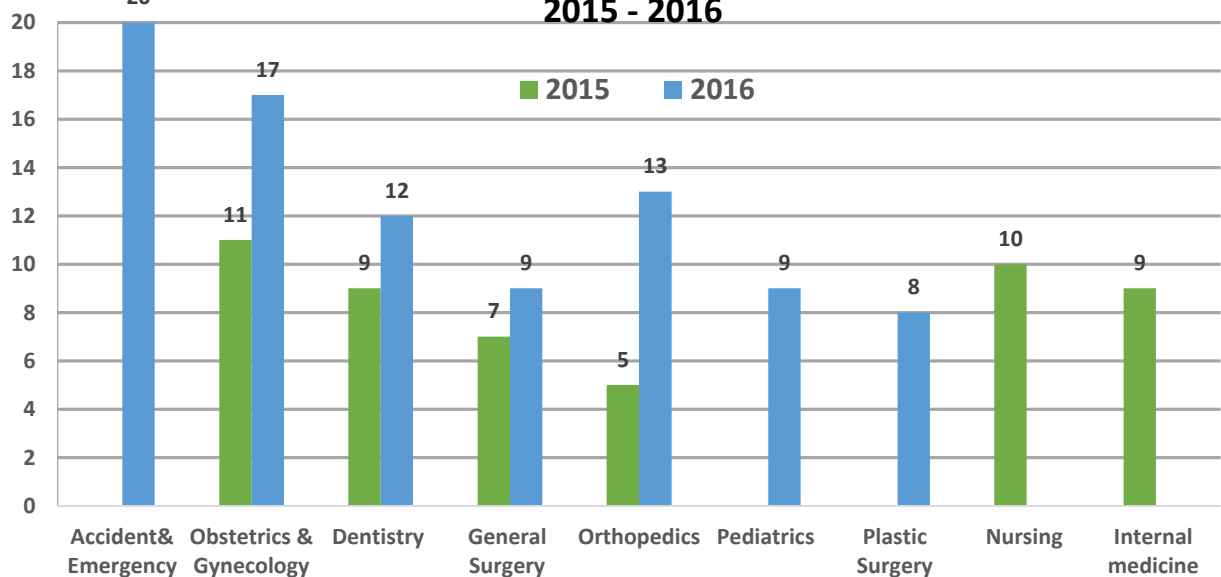
In 2016, the complaints department received 171 claims of medical error or violation of the principles, duties, requirements and ethics of practicing health professions. Out of these, 111 were healthcare related complaints from individuals (patients / relatives), 60 were incident reports received directly from healthcare facilities / professionals, and 37 health related law suits were referred by the public prosecutor or from the courts. *The distribution of these complaints are summarized in Figures (29) and (30) below:*



**Figure (29) Distribution Of Complaints by Health Profession  
2015 - 2016**



**Figure (30) Distribution of Complaints by Medical Speciality  
2015 - 2016**

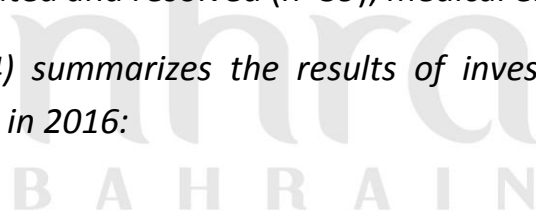


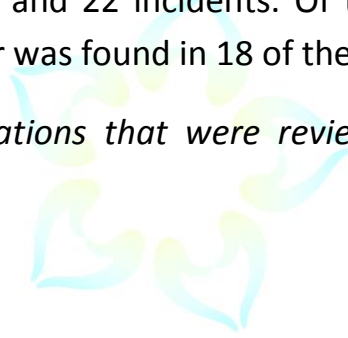
Some of the challenges this department faces in meeting its goals is the frequency and timing of the resolution committee meetings, the increased number of complaints received over the past year and the increased response times to documentation/evidence requests from healthcare providers or centers. These challenges have resulted in considerable delays to the outcomes of cases received from all channels.

To address these challenges the department is working on putting in place processes that aim to reduce the volume of information presented at the weekly committee meetings by forming sub technical group meetings to review the documentation beforehand. In addition to this the frequency of the weekly committee meetings may be increased in the coming year.

Out of the 171 cases received in 2016, the medical complaints unit has completed the investigation of 37 complaints and 22 incidents. Of the cases investigated and resolved (n=59), medical error was found in 18 of these cases.

*Table (4) summarizes the results of investigations that were reviewed and resolved in 2016:*

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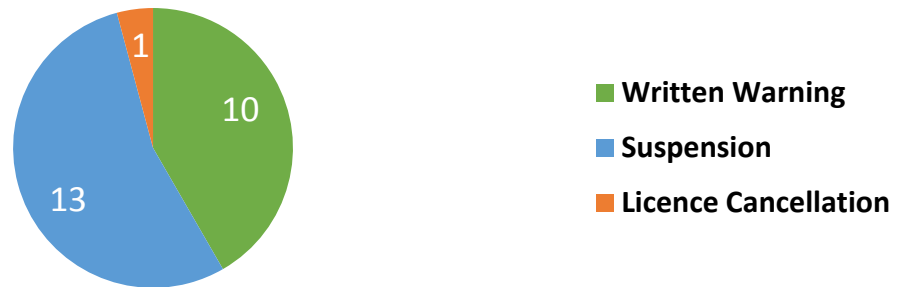
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<b>Result</b>	<b>Complaints from individuals</b>	<b>Incidents</b>	<b>Total</b>
<b>No medical error or violation of the principles, duties, requirements and ethics</b>	<b>15</b>	<b>6</b>	<b>21</b>
<b>Referred to disciplinary committees</b>	<b>4</b>	<b>8</b>	<b>12</b>
<b>Transferred to law suits registry</b>	<b>4</b>	<b>2</b>	<b>6</b>
<b>Closed for failure of interpolation of information</b>	<b>4</b>	<b>-</b>	<b>4</b>
<b>Referred to concerned party outside NHRA</b>	<b>1</b>	<b>-</b>	<b>1</b>
<b>Not within jurisdiction of NHRA</b>	<b>4</b>	<b>2</b>	<b>6</b>
<b>Referred to public prosecution</b>	<b>2</b>	<b>1</b>	<b>3</b>
<b>Regulatory violation, amendment done</b>	<b>3</b>	<b>3</b>	<b>6</b>
<b>Total</b>	<b>37</b>	<b>22</b>	<b>59</b>

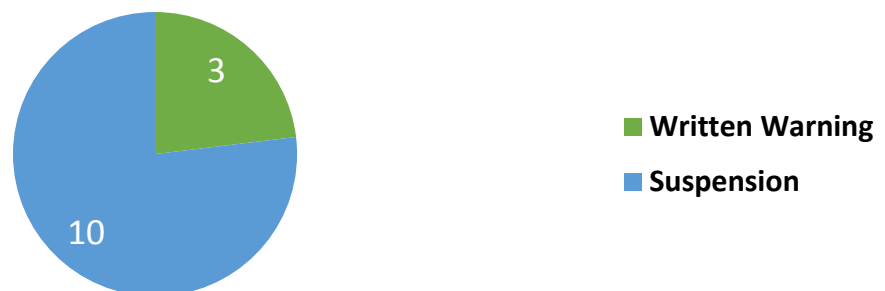
**Table (4): Summary of Complaints Resolved by NHRA – 2016.**

Furthermore, a total of (43) disciplinary decisions were issued by various disciplinary committees at NHRA in 2016. Of the 43 disciplinary actions taken, 24 were against doctors, 13 against nurses and 6 against allied health professionals. *Figures (31) – (33) demonstrate the disciplinary actions taken by NHRA.*

**Figure (31) Disciplinary Actions Taken Against Doctors**



**Figure (32) Disciplinary Actions Taken Against Nurses**



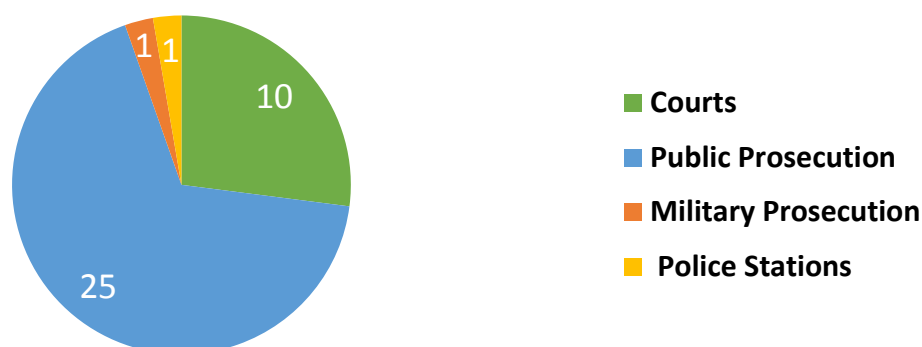
**Figure (33) Disciplinary Actions Taken Against Allied Health Professionals**



## Lawsuits

In 2016, NHRA received a total of (37) cases referred by courts, the Public Prosecution and Military Prosecution, out of which (12) has been investigated. *Figure (34) shows the distribution of lawsuits by source.*

**Figure (34) Source of Lawsuits - 2016**

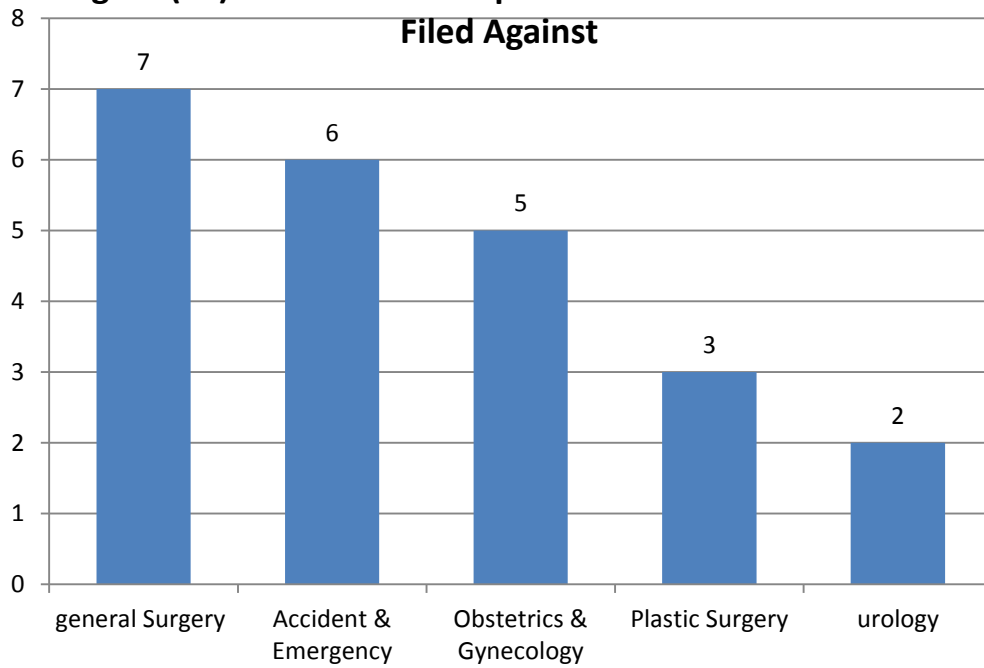


Of the (12) total cases investigated, (7) were found to have medical error/negligence, while the other (5) were found to have no evidence of negligence in the management. Twenty-five lawsuits are still pending investigations. *Table (5) below summarizes the status of lawsuits investigated (n=12) and Figure (35) demonstrates the most common specialties that have lawsuits filed against them.*

Sector	Investigated	
	Medical Negligence / Error Not Proved	Medical Negligence / Error Proved
Public (7)	(4)	(3)
Private (5)	(1)	(4)

**Table (5): Outcomes of Lawsuits Investigated**

**Figure (35) Most Common Specialities That Lawsuits Are Filed Against**



## Regulating Clinical Trials



**NHRA Clinical Trial Committee**

NHRA is mandated by law to regulate, promote, authorize and oversee the conduct of clinical trials in the Kingdom of Bahrain.

NHRA's primary objective is to ensure that the conduct of clinical/trials research is supported by adequate ethical, scientific, regulatory and legal frameworks, and, that human subject protection is a shared responsibility within the clinical trials/research enterprise.

In implementing its strategy and asserting its authority, NHRA has issued the following regulations governing the planning, execution and reporting of clinical trials;

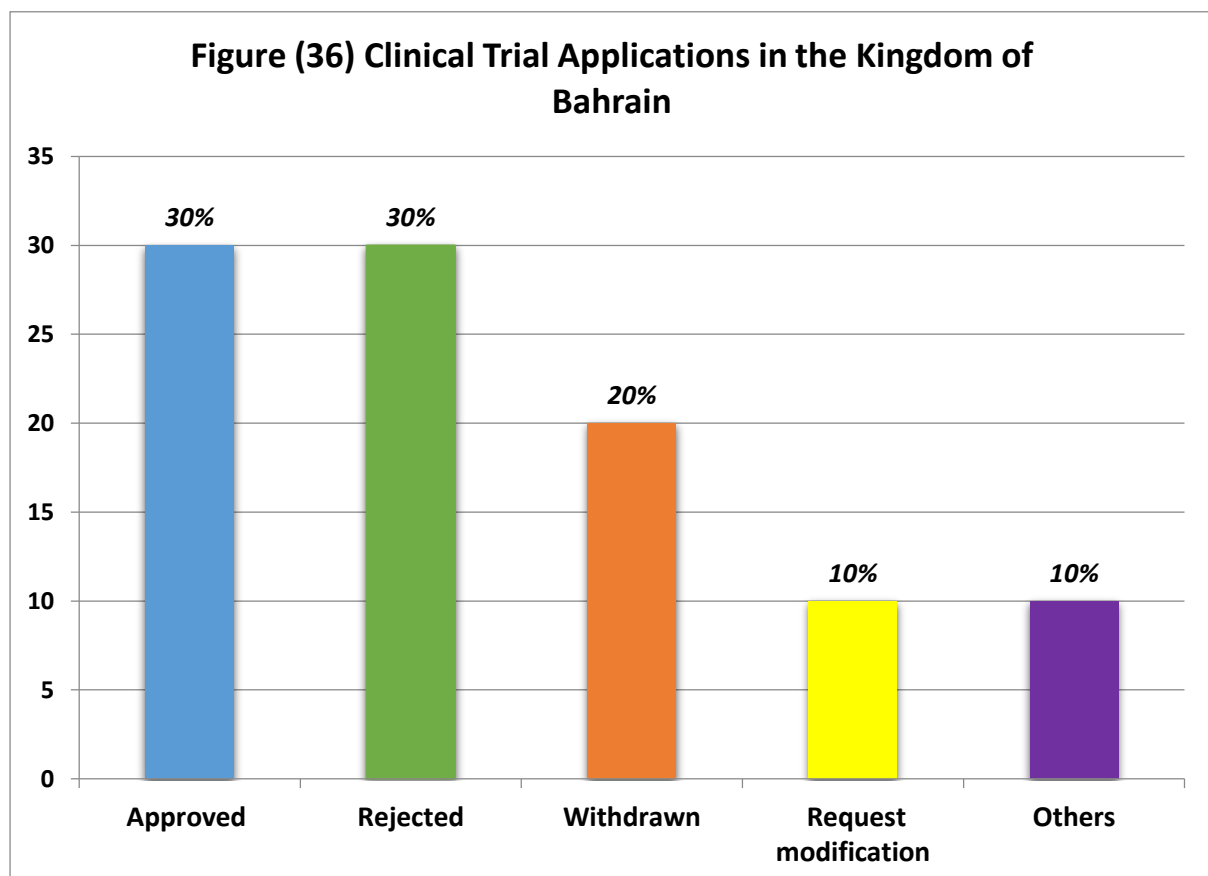
- Regulatory Requirements for clinical trials in the Kingdom of Bahrain
- Requirements for Independent Research Ethics Committee (IREC) involved in Clinical Trials in the kingdom of Bahrain.
- Clinical Trials Regulations document.

The current regulation is based on international regulations and standards on Good Clinical Practice, provided by leading regulatory bodies like World Health



organization (WHO), U.S Food & Drug Administration (FDA), EMA (European Medicines Agency) and International Conference of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH).

To date, (10) research proposals have been reviewed by the NHRA Clinical Trials Committee of which; (3) have been granted approval and (2) have been withdrawn by the applicants. Three (3) trials have been rejected as (2) of them were studies on stem cells, which is not an approved practice in the Kingdom of Bahrain and (1) study did not meet NHRA Clinical Trials standards and regulations. *Figure (36) below demonstrates the status of clinical trial applications in the Kingdom of Bahrain.*





## **Accrediting Continuous Professional Development Programs**



### **Continuous Professional Development (CPD) Committee**

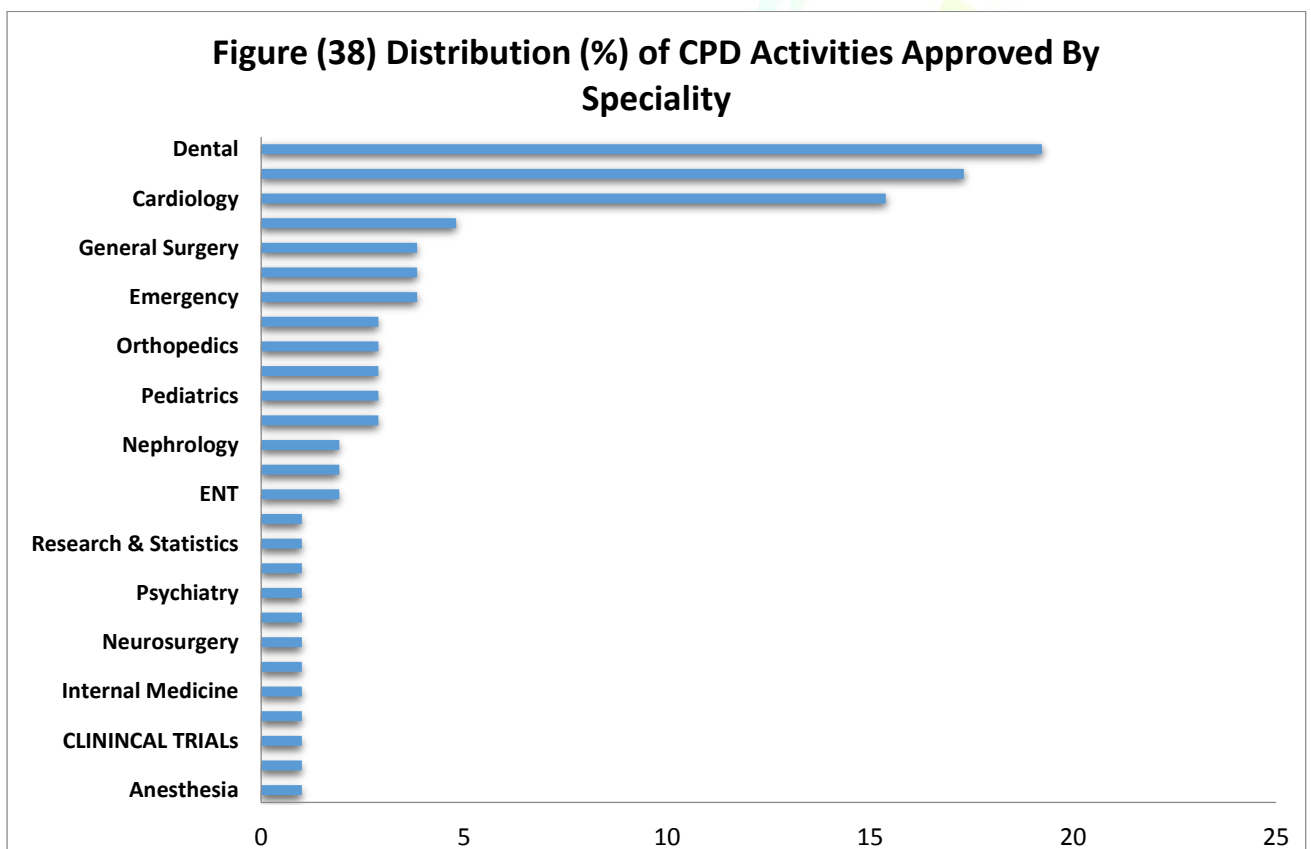
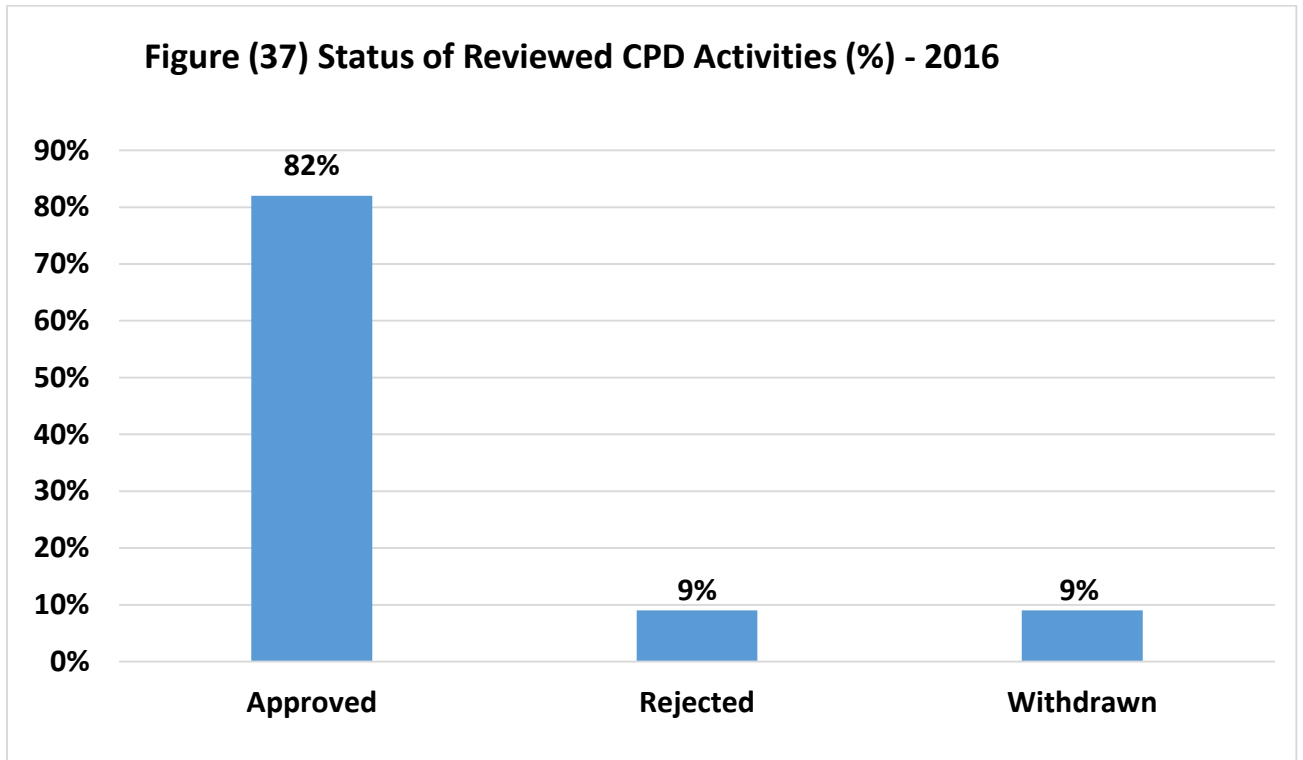
Continuous professional development programs aim to communicate up to date knowledge, health skills and new developments in medicine, dentistry, alternative medicine and allied health in the Kingdom of Bahrain. Continuous Medical Education (CME) and Continuous Professional Development (CPD) are a lifelong learning process that complement formal education and training of healthcare professionals. This learning process may include medical, managerial, ethical, social and personal communication skills on top of specialty-based competencies.

In May 2016, the Supreme Council of Health authorized NHRA to start implementing the National Continuous Professional Development program. A CPD accreditation committee was formed in June 2016 by the authority of NHRA CEO and this committee developed the charter and guidelines for submitting and reviewing CPD programs.

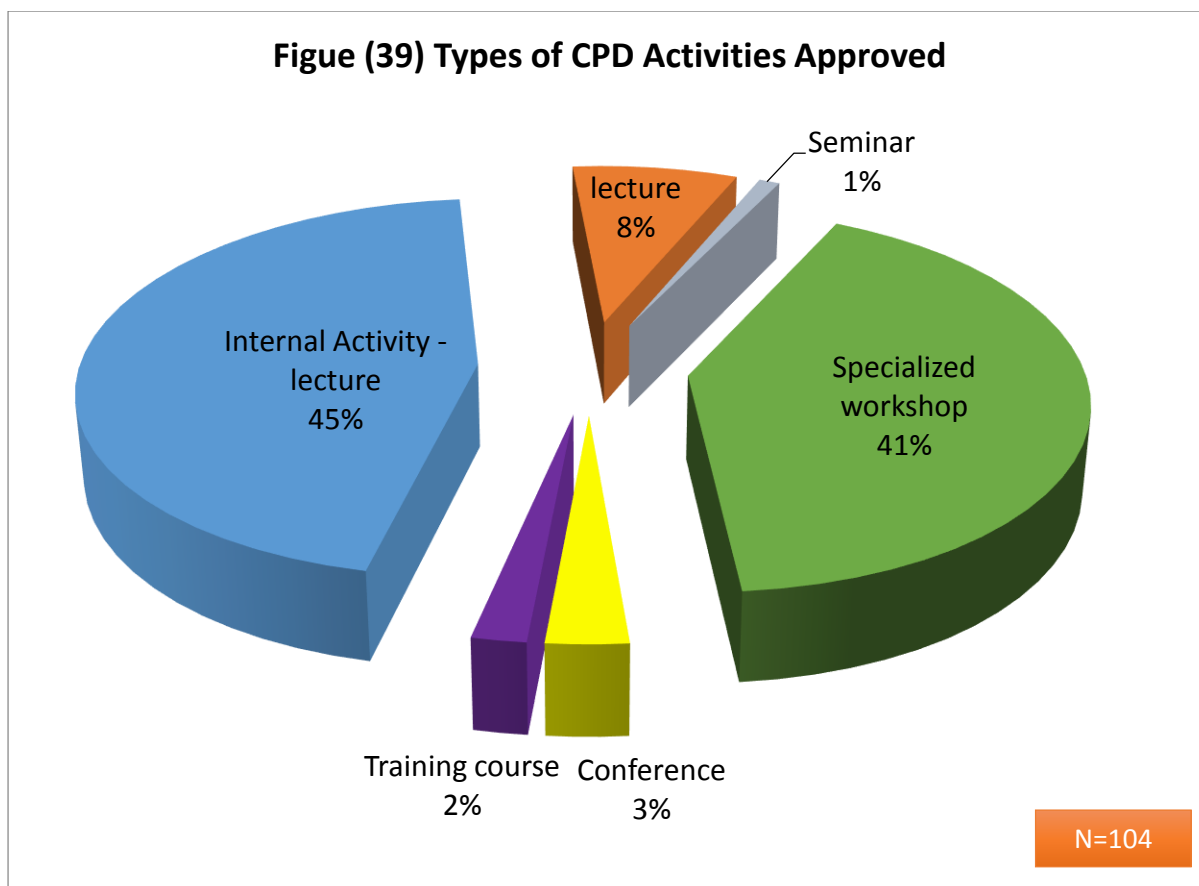
This initiative has been communicated to all private and governmental healthcare facilities and application forms are available on the NHRA website.

From its inception, the committee has reviewed (127) CPD programs and approved (104) of them.

Figures (37) - (39) below outline the activities of the Continuous Professional Development (CPD) Committee:



**Figure (39) Types of CPD Activities Approved**



In the next couple of months of 2017, the plan is to link CPD accredited hours to professional licensing thereby ensuring value to CPD hours attained by healthcare professionals in the Kingdom. The CPD committee is also actively seeking to fulfill any unmet needs of education with the requirements of the upcoming National Accreditation Program.

## ***National Accreditation for Health Care Facilities***

The concept of accreditation came about in response to the ratification of Law no. (21) in 2015, which specified, in Article 19 that NHRA is responsible for reviewing and evaluating the health services in all facilities to ensure quality of those services, ensure highest performance and ensure compliance with regulations and standards related to patient safety, infection control and other technical preparedness.

In order to implement Article 19, the Supreme Health Council issued decision No. (7) in 2016 specifying the required NHRA standards, and subsequently issued Decision No. (26) in the same year regarding the accreditation of health care facilities in the Kingdom of Bahrain.

NHRA conducted a training workshop to certify surveyors in the field of hospital accreditation. The training was held by the Saudi Central Board for Accrediting Health Institutes (CBAHI). The Workshop was held over 5 days and attended by 86 participants. At the end of the workshop the participants were awarded an attendance certificate which certifies them to conduct surveys for accreditation.

NHRA has issued The National Accreditation policy and will start implementation in private hospitals in the first quarter of 2017.



Surveyor Training Program Conducted by Saudi Central Board for Accrediting Health Institutes (CBAHI)

## Scientific Activities

NHRA has conducted five scientific meetings in 2016, as follows:

### 1. GCC Complementary and Alternative Medicine (CAM) Regulation Meeting held on 12-13 April 2016.

NHRA sponsored a Gulf Cooperation Council (GCC) meeting in April to adopt unified regulations in complementary and alternative medicine in the member states. The unified GCC CAM regulation proposed by NHRA standardizes the requirements for licensing CAM Facilities, alternative products, and practitioners. These regulations have been adopted by the GCC Executive Board and are awaiting the final endorsement by GCC ministers of health.



### 2. The First Joint Scientific Forum on Clinical Trials held on 11 February 2016.

NHRA held the first joint scientific forum on clinical trials titled "Capacity-Building and Encouraging Responsible Behavior for Clinical Trials." This forum was held in partnership with the Arabian Gulf University and participant's represented both private and governmental hospitals and pharmaceutical companies. This forum highlighted the importance of adopting national criteria to help facilitate the ethics research committees that approve clinical trials in health care institutions.





### 3. Lectures on Professional Regulation of Nursing Practice.

NHRA conducted annual lectures on professional regulation of nursing practice and legal issues in nursing in the Kingdom of Bahrain. NHRA also participated at the Royal College of Physician and Surgeons Ireland (RCSI) nursing careers day. The process of nursing licensure was reviewed for new graduates entering the workplace.



CHS - May 2016



RCSI- October 2016

### 4. Infection Control Workshop held on 15 April 2016.

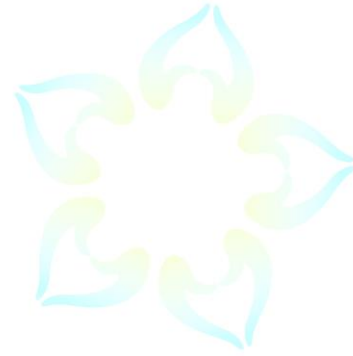
NHRA in collaboration with the infection control section of the Ministry of Health conducted a workshop on infection control procedures that should be adhered to in dental clinics. More than 40 participants attended from the private sector. The needs of the participants, in terms of infection control, were identified and reviewed. The workshop encompassed discussion on policies and procedures of infection control and included both theoretical and clinical training.



## **5. The Second Joint Scientific Forum on Clinical Trials held on 23 -24 November 2016**

NHRA in cooperation with the Arabian Gulf University held the second scientific meeting, 'Harmonizing Clinical Trials Regulations in the GCC'. During the summit, GCC representatives discussed the proposal submitted by the Kingdom of Bahrain and the Kingdom of Saudi Arabia that constituted the 'Guidance for Conducting Clinical Trials on Drugs in GCC Countries: Harmonization of Key Regulatory Requirements.' As a result of the meeting the GCC representation have adopted the proposed regulations and have raised them to the GCC Ministers of Health Board for adoption.

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## **Regulatory Activities**

NHRA has participated in the following meetings related to various regulatory activities conducted in 2016:

1. EMRO Drug Regulation Meeting
2. Joint GCC Mission To China
3. GCC Medical Device Regulation
4. GCC Drug Registration Committee Meeting
5. EMRO Drug Regulation Meeting

The Joint GCC mission to China was held on 25 – 26 July 2016 in Beijing, China. A joint GCC team met with traditional Chinese medicine specialists aiming to understand different aspects of traditional Chinese medicine, and to explore recommendations to recognize the practice under the free trade agreement being negotiated between the GCC and China.





## ***Meeting with Our Stakeholders***

### **1. Meeting Complementary & Alternative medicine (CAM) practitioners**

NHRA held a meeting for CAM practitioners in the Kingdom of Bahrain to discuss the development of new standards and regulations. Participants concerns on the obstacles and challenges were considered whilst developing the standards. NHRA wishes to extend its' appreciation to all those who participated and shared their valuable viewpoints.



### **2. Meeting with Private Hospitals**

NHRA met with all private hospital directors to discuss the upcoming National Accreditation Program. The hospital directors expressed their appreciation for NHRA's approach to involve the private sector in the discussion and share their views in the implementation process. Hospital leadership also acknowledged and appreciated the recent process improvements at NHRA that have considerably decreased the wait times of licenses for healthcare professionals.



### 3. Meeting with Pharmaceutical Agents and companies

Several meetings were held with pharmaceutical agents and companies to discuss medical devices and drug customs release and registration regulations.



### 4. Meeting with Tamkeen.

NHRA and Tamkeen discussed areas of collaboration in training and supporting continuous professional development programs in the private health sector.



### 5. Meeting with IGA

NHRA is collaborating with information and e Government Authority to develop its IT system. Several meetings were held to discuss NHRA process requirements; both teams will continue to cooperate to develop a comprehensive system that will enhance NHRA services and procedures.



#### **6. Meeting with Economic Development Board EDB**

NHRA discussed mutual collaboration with EDB and was in attendance of several meetings hosting investors looking for opportunities in the health sector in Bahrain.

#### **7. Meeting with Optometry Facilities.**

NHRA hosted a meeting with optometry facility owners. The following points were reviewed and discussed:

- Issues concerning the licensing and regulation of the profession and facilities
- The possibility of increasing the number of exams per year and the years of experience required to be licensed
- Amendment of the current regulation related to optometrists licensing in order to overcome the current shortage of optometrists in the Kingdom

The participants expressed their gratitude to the current developments in NHRA that was reflected in the speed of issuing licenses of both professionals and facilities.



## ***Equal Opportunities***



**Members of NHRA Equal Opportunity Committee**

NHRA values its entire staff equally, regardless of gender and promotes a work environment where individuals are treated with fairness, respect, equality and dignity. NHRA has worked collaboratively with the Supreme Council of Women (SCW) to increase capacity building and awareness around equality to ensure that our staff is fully informed of the concepts developed by the SCW.

The Equal Opportunity Committee was formed in response to Decision no. 50 in 2016. This committee was established to help raise awareness of legal rights, to ensure equality and to be a resource for women to



understand their rights.

In 2016 the committee conducted the following activities:

1. On 4 January 2016 a questionnaire was distributed to all staff to gather information about NHRA staff awareness of the SCW's goals.
2. On 20 April 2016 the Committee participated in the 1<sup>st</sup> meeting of the General Secretariat of the SCW.
3. On 19 July 2016 NHRA staff participated in the 2<sup>nd</sup> meeting with the Secretariat of the SCW.
4. On 24 July 2016 analysis of the staff awareness initiative was conducted.
5. On 17 November 2016 NHRA in collaboration with SCW conducted a legal symposium on the general framework for the rights of women and the most important laws and decisions in support of the integration of women's needs. On the occasion of Bahraini Women's day, all judicial officers of NHRA were honored at a ceremony to mark the day.
6. The committee members also participated in the framework of preparations for celebrating Bahraini women's day 2016 which honored "women in the legal field and courts."
7. On 1 - 3 November 2016 the committee participated in the 3<sup>rd</sup> Conference of Bahraini women - 'Women and Law Completion: The Challenges and Aspirations'.
8. Two surveys were conducted by the committee - the first was to measure the awareness of NHRA employees regarding the purpose of the equal opportunity committee, and the second aimed to improve and strengthen women in the NHRA, government and the private health sector.





“Achieving competitiveness in all sectors and all levels through the empowerment of NHRA employee’s to their rights and duties, plus to encourage the integration of women in development programs”



## The Way Forward

This past year the government has issued numerous legislations that place value on the ethos of safe healthcare across the care continuum for the people of Bahrain. We, at NHRA, wholly subscribe to the principles that these laws are founded upon and indeed our own 5 year plan is built on the very same principles, which we have prioritized as our strategic goals.

We recognize that improving healthcare is a partnership and that respectful collaboration is at the heart of it. With the National Accreditation Program set to be implemented in the second quarter of 2017 we are optimistic that NHRA's journey to fulfill its strategic priorities has already begun and will only improve with time. We are committed to working with hospitals to help them attain a standard that provides safe and trusted health services with patient safety as a top priority.

We will continue to improve our processes and procedures and plan to have a fully integrated IT system by the end of 2017. This system will streamline regulatory functions such as online licensures exams, renewal of licenses and drug registration. This system will also allow us to extend our drug safety monitoring function and initiate the Pharmacovigilance Program of Bahrain.

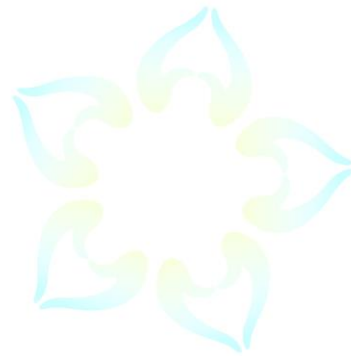
Towards the end of 2017 our plan is to incorporate the renewals of professionals' licenses to their CPD accredited hours attended. This will allow

us a way to track the continuous education of healthcare professionals and streamline the process of renewals.

This coming year presents us with opportunity to transform healthcare. We fully intend to seize this opportunity and become a trusted partner to healthcare organizations and patients in the Kingdom of Bahrain.



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