Kingdom of Saudi Arabia
Saudi Food & Drug Authority

A new Era of Medical Devices Regulation in Saudi Arabia

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Saudi Food & Drug Authority

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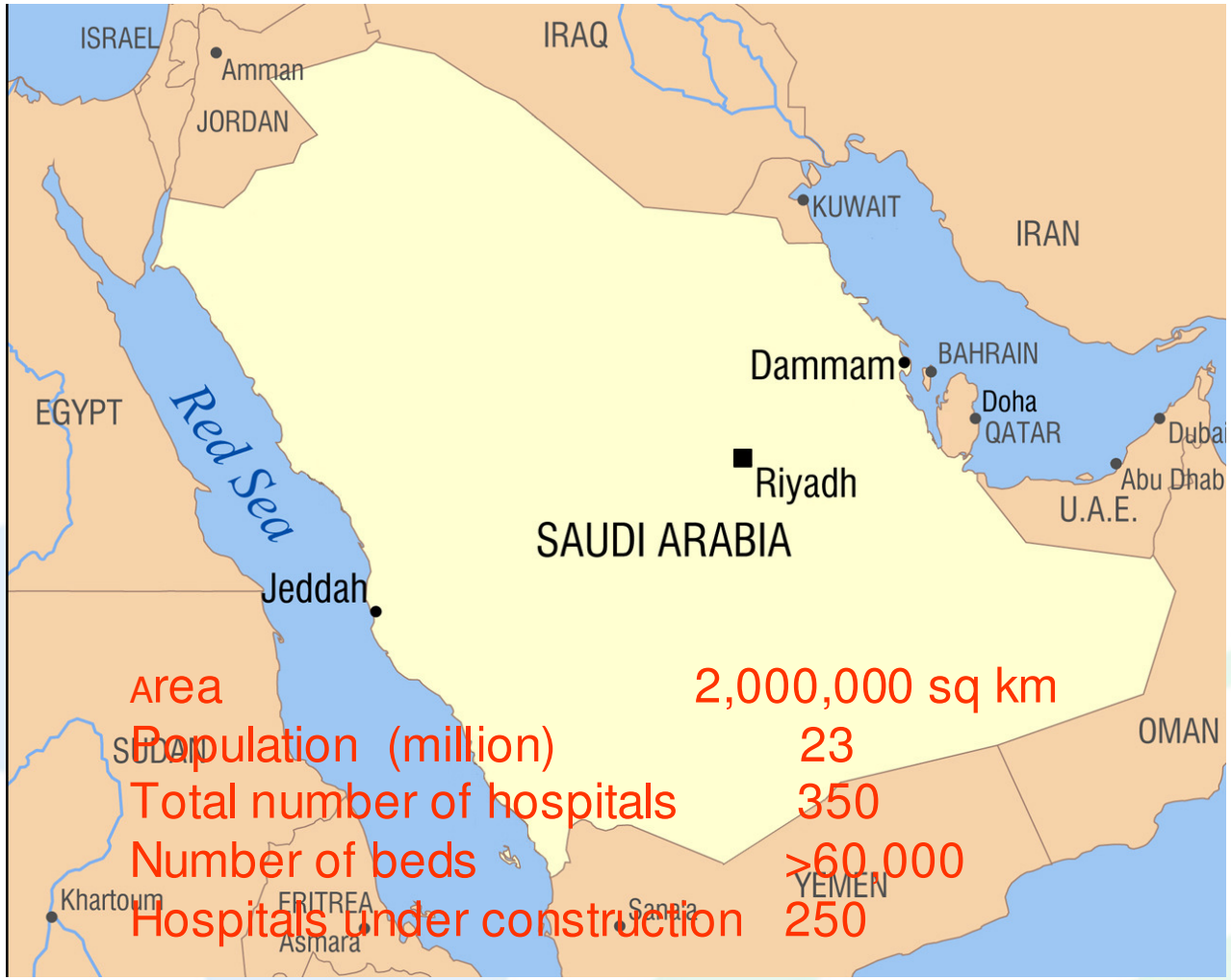

ISRAEL
Amman
JORDAN
IRAQ
KUWAIT
IRAN
Dammam
BAHRAIN
Doha
QATAR
Dubai
Abu Dhab
U.A.E.
EGYPT
Red Sea
Riyadh
SAUDI ARABIA
Jeddah
OMAN
SUDAN
Khartoum
ERITREA
Asmara
Sana'a
YEMEN
Area 2,000,000 sq km
Population (million) 23
Total number of hospitals 350
Number of beds >60,000
Hospitals under construction 250

Agenda

- Introduction
- Medical Devices Interim Regulation (MDIR)
- Medical Devices Implementing Rules (IRs)
- Medical Devices Electronic Services (MDES)
- International Achievements
- On Going Projects

Introduction

- The Saudi Food & Drug Authority (SFDA) was established under the council of ministers resolution no (1) dated March 10, 2003.

- A royal decree was issued on Feb. 13, 2007 to establish the law of SFDA.

- A council of ministers resolution no (18) was issued on June 18, 2007 giving the SFDA a full authority to regulate the medical device market in Saudi Arabia.

- SFDA reports directly to the premier of the council of ministers.

Introduction (cont)

- **It has a board of director consisting of 18 member headed by:**

HRH Prince
Sultan bin Abdulaziz,
Crown Prince, Second Deputy Premier, Minister of Defense, Aviation and the Inspector General

Introduction (cont)

- SFDA is an independent body with independent budget.

- The Authority objective is to ensure safety of Food and Drug for human and animal, Safety and quality of Medical Devices, and safety of biological and chemical substance as well as electronic products.

Medical Devices Interim Regulation (MDIR)

- The SFDA has adopted A Medical Devices Interim Regulatory System that complies with GHTF guidance.
- The Medical Devices Interim Regulation was issued by the SFDA Board of Directors Decree number 1-8-1429 on 27th December 2008.
- The Medical Devices interim regulation was developed in cooperation with a group of experts in medical devices regulations in cooperation with the world bank.

Medical Devices Interim Regulation (MDIR) (cont)

- **The Purpose of the Medical Devices Interim Regulation is to: (chapter One, Article Two of MDIR)**

  ✓**Protect and maintain public health within the KSA by the implementation of provisions ensuring a high level of safety and health protection of patients, users and third parties with regard to use of medical devices as it relates to their manufacture, supply and use during their lifecycle.**

Medical Devices Interim Regulation (MDIR) (cont)

✓**Mandate measures, and allocate responsibilities, to ensure that medical devices placed on the market and/or put into service within the KSA comply with the relevant provisions of the Interim Regulation.**

Medical Devices Interim Regulation (MDIR) (cont)

- **The medical devices interim regulation applies to the following: (Chapter One / Article Three of MDIR)**
  - ✓ **Manufacturers, authorized representatives , importers, and distributors.**
  - ✓ **All medical devices and their accessories that will be supplied to the KSA market.**
  - ✓ **Contact lenses and laser surgical equipment for cosmetic rather than medical purposes, and their accessories.**

Medical Devices Interim Regulation (MDIR) (cont)

- **Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation as signified by the SFDA issuing the manufacturer with a written Marketing Authorization. (Chapter Two, Article Four, MDIR)**

- **Manufacturers established within KSA, authorized representatives, importers and distributors of medical devices shall: (chapter Four, Article Ten, MDIR)**
  - ✓ **Register their establishments with SFDA.**
  - ✓ **List medical devices with SFDA.**

Medical Devices Interim Regulation (MDIR) (cont)

- **A Manufacturer located in the KSA or an Authorized Representative may at the same time act as the importer and/or distributor of medical devices. (Chapter Four, Article Twelve, MDIR)**

- **Local manufacturers involved in distribution activities, as well as importers, distributors and authorized representatives involved in importation or distribution activities, shall apply for an establishment license. (Chapter Five, Article Fifteen A, MDIR)**

Medical Devices Interim Regulation (MDIR) (cont)

- **The Manufacturer or its Authorized Representative shall for the medical device it wishes to place on the market of the KSA comply with Article Eighteen of chapter SIX, MDIR.**

Medical Devices Interim Regulation (MDIR) (cont)

- While retaining in full the responsibilities placed upon it by the regulations, the SFDA may designate conformity assessment body (third party) to assist in carrying out some of its duties in this Interim Regulation(Chapter Seven, Article Twenty Three, MDIR)

- A number of Conformity Assessment Bodies (CABs) have been selected and negotiation is going on to contract them to work with SFDA on pre-market approval.

Medical Devices Interim Regulation (MDIR) (cont)

- **A Conformity Assessment Bodies designation document has been published.**

- **Where the SFDA has reason to believe a manufacturer, an authorized representative or any other party in the supply chain of a medical device has made a misleading or fraudulent claim of the medical device, it shall investigate and take action as appropriate to the circumstances. (Chapter Eight, Article Thirty, MDIR)**

Medical Devices Interim Regulation (MDIR) (cont)

- **The SFDA shall monitor the use of medical devices in the KSA and take the appropriate measures to ensure their proper installation and maintenance in respect of the safety of patients, users and other persons. (Chapter Eight, Article Thirty Five, MDIR)**

Medical Devices Interim Regulation (MDIR) (cont)

- **Where the SFDA has evidence to suggest that health and/or safety of patients or users is compromised despite the medical device have been lawfully supplied to the market of the KSA, it reserves the right to require the device to be withdrawn, or restricted in some manner. (Chapter Nine, Article Thirty Six, MDIR)**

Medical Devices Interim Regulation (MDIR) (cont)

Advertisement of medical Devices is covered under (Chapter Ten, Article 39, MDIR):

- **The advertising of a medical device for which the SFDA has not issued a marketing authorization is prohibited.**
- **All advertisement material must be approved by SFDA.**
- **The advertising material shall not mislead the user regarding the performance of the medical device as specified by the manufacturer.**

Medical Devices Interim Regulation (MDIR) (cont)

- **The advertising to the general public, including on the internet, shall avoid misleading lay persons.**

- **Any advertising to persons qualified to use medical devices shall include the relevant information compatible with their specific needs.**

- **Medical sales representatives shall have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.**

Medical Devices Interim Regulation (MDIR) (cont)

- **The SFDA reserve the right to take the appropriate actions when any of the interim measures are violated such as: (Chapter Eleven, Article Forty, MDIR)**
  - ✓ **Suspend the license.**
  - ✓ **Terminate the license.**
  - ✓ **Recall the product from the market.**
  - ✓ **Withdrawn of the marketing authorization.**

Implementing Rules (IRs)

- **A set of Implementing Rules (IRs) has been / will be published by the MDS-SFDA.** ***These implementing rules are administrative methods used as a part of medical device regulation as a force of law.***

- ***They should be relied on, to ensure medical devices placed on the market of the KSA will achieve an appropriate level of safety and performance with regard to the manufacture, supply and use of medical devices, to address every aspect of relevant legislation.***

Implementing Rules (IRs)

Electronic Services

The MDIR is facilitated through a set of electronic systems and solutions to enable Manufacturers, Authorized Representatives, Importers, Distributors, and other parties to communicate efficiently with the MDS/SFDA.

قواعد معلومات
الأجهزة والمنتجات الطبية
MDDB
Medical Devices Databases

السجل الوطني للأجهزة
والمنتجات الطبية
MDNR
Medical Devices
National Registry

نظام الترخيص الالكتروني لمنشآت
الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishement Lecince

المركز الوطني للبلاغات
الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical
Devices Reporting

الخدمات الالكترونية للأجهزة الطبية
MDES
Medical Device Electronic Services

SNS
نظام الإبلاغ المسبق
Shipment Notification System

ترخيص الأجهزة الطبية
MDL
Medical Devices Licensing

Medical Devices National Registry (MDNR)

- **Medical Devices National Registry (MDNR) is a web-based enrollment scheme for medical devices establishments, manufacturers, agents and suppliers in Saudi Arabia, where all applications are made on-line.**

Medical Devices National Registry (MDNR) (cont)

- **Local manufacturers, authorized representatives, importers, and distributors of medical devices must register their establishment and list their devices in the MDNR, and must comply with chapter 4 MDIR , MDS-IR2 Medical Devices Establishment Registration , and MDS-IR3 on Medical Devices Listing).**

Medical Devices National Registry (MDNR) (cont)

- **It aims to:**

✓**Collect and maintain the information required for medical devices establishment registration and medical devices listing.**

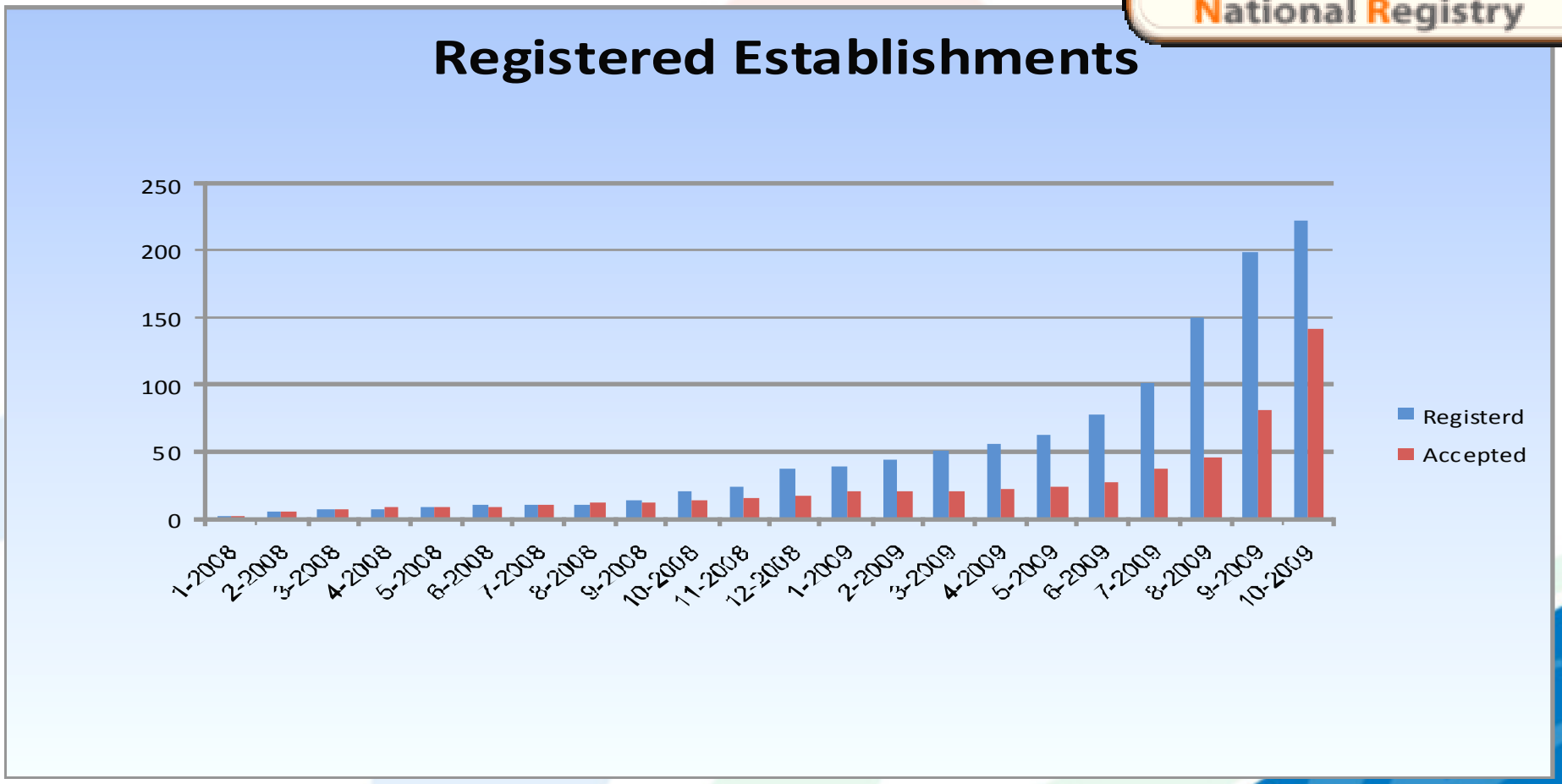
✓**To establish and maintain a profile of the KSA medical devices market.**

Medical Devices National Registry (MDNR) (cont)

- ✓To provide information on the establishments involved in the manufacture or the supply of medical devices intended for the KSA.
- ✓To provide information on medical devices that will be supplied to the KSA.
- ➢The system was launched on November 2007.

Medical Devices National Registry (MDNR) (cont)

السجل الوطني للأجهزة والمنتجات الطبية
MDNR
Medical Devices National Registry



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Medical Devices National Registry (MDNR) (cont)

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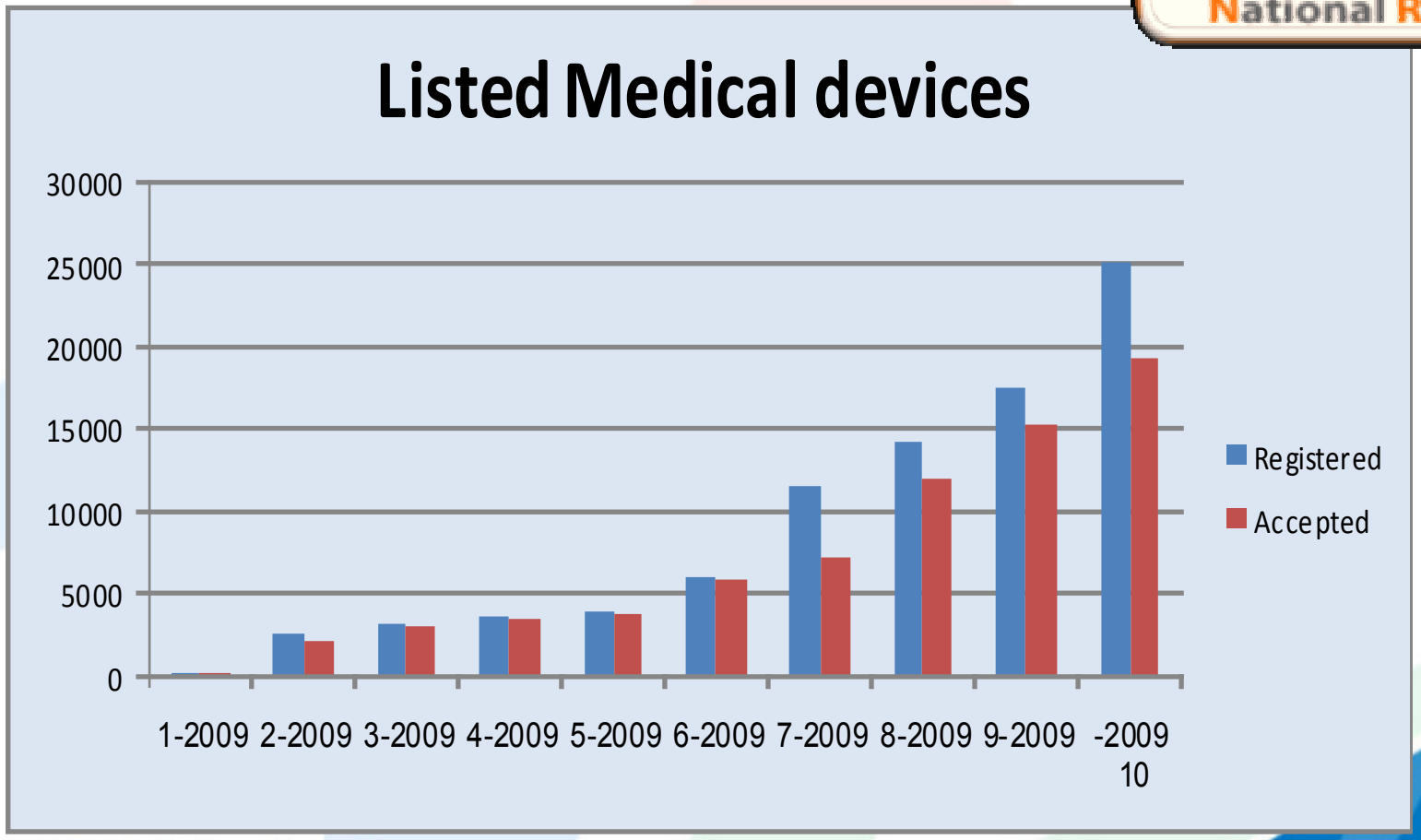
MDNR
Medical Devices National Registry



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Medical Device Establishment Licensing System (MDELS)

- **Medical Devices Establishments Licensing System (MDELS) is a web based system to facilitate licensing of medical devices establishments in Saudi Arabia, where all applications are applied on line.**

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Saudi Food & Drug Authority

Medical Device Establishment Licensing System (MDELS) (cont)

- Local manufacturers involved in distribution activities, importers, distributors, and authorized representatives involved in importation or distribution activities must apply for establishment license. (chapter 5 MDIR).

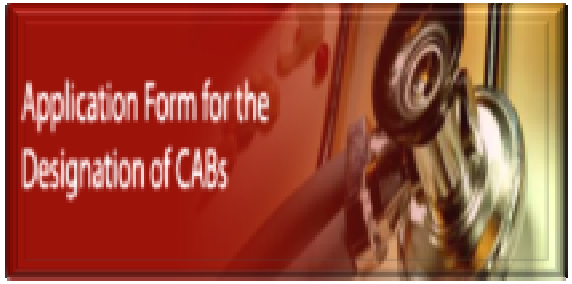
- Establishments must comply with the requirements of chapter 5 MDIR, and MDS-IR4 on Medical Devices Establishment Licensing.

Designation of Conformity Assessment Bodies

- The candidate CAB shall apply to the SFDA in writing and shall complete all the required information on line.

- A number of Conformity Assessment Bodies (CABs) have been selected and final negotiation is going on to contract them to work with SFDA on pre-market approval.

Designation of Conformity Assessment Bodies (cont)



- Conformity Assessment Bodies(CABs) established in Saudi Arabia are expected to review and evaluate the adequacy of the documentation provided to the SFDA by the manufacturer for obtaining Marketing Authorization.
- The candidate CAB shall comply with all applicable requirements of chapter 7 of MDIR and MDS-IR1 on CABs Designation)

Shipment Notification System (SNS)

- **Shipments Notification System (SNS) is an Online system used by Importers of Medical Devices to notify SFDA about the upcoming shipments, and the port of entry that it will arrive through.**

Designated Ports Of Entry (DPOE)

- **Medical Device Sector is fully operational at the nine designated Ports Of Entry (MDPOE) to work next to Saudi customs.**
- **The role of MD personnel is to ensure that MD imported to Saudi Arabia are SFDA approved and fulfill the SFDA requirements and the manufacturer instructions for storage and handling.**

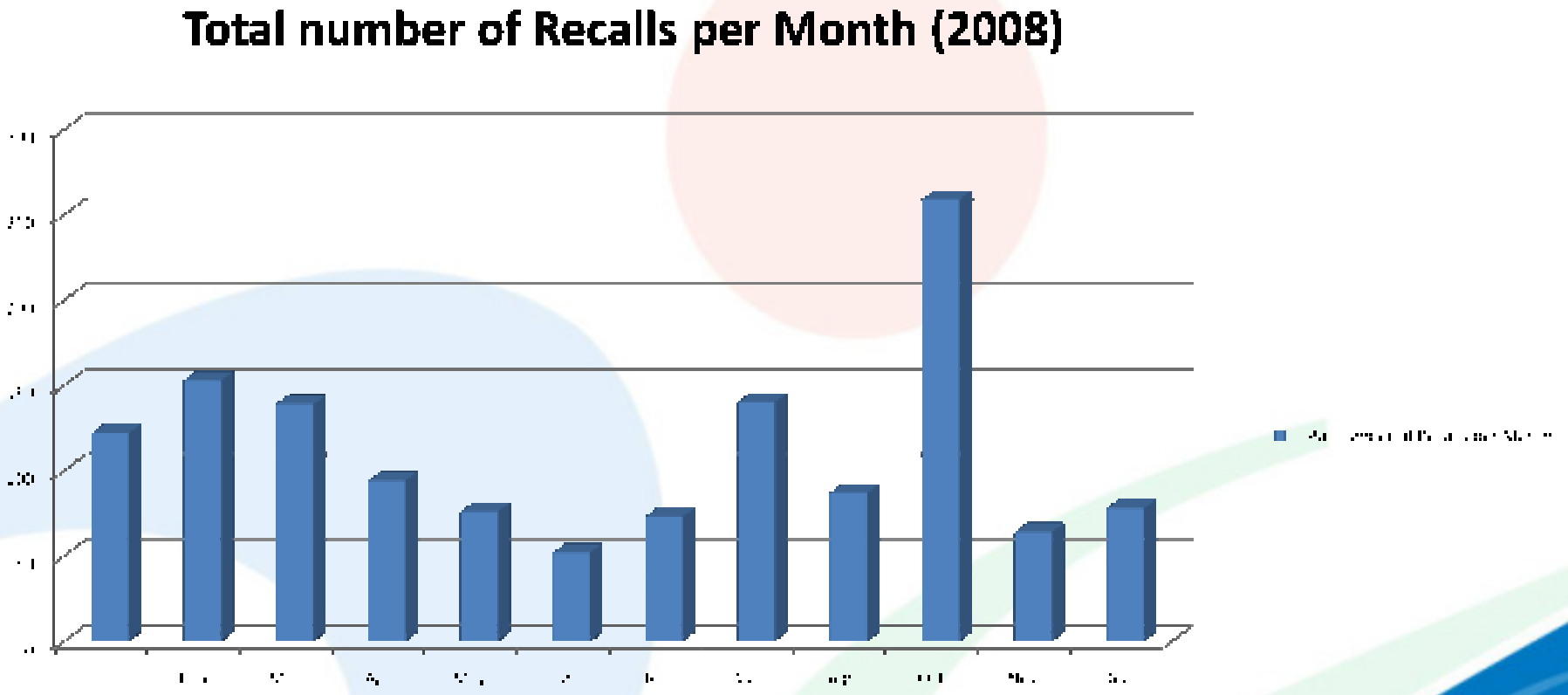
National Center For Medical Device Reporting (NCMDR)

- **National Center for Medical Devices Reporting (NCMDR) is an organization managing a database of information on safety and performance related aspects of medical devices and capable of taking appropriate action on any confirmed problems.**

National Center For Medical Device Reporting (NCMDR) (cont)

- It is A web based system developed in cooperation with ECRI, where all applications are submitted on line.
- It was Lunched on Dec 2007.
- It is a member of NCAR and SADS.

National Center For Medical Device Reporting (NCMDR) (cont)



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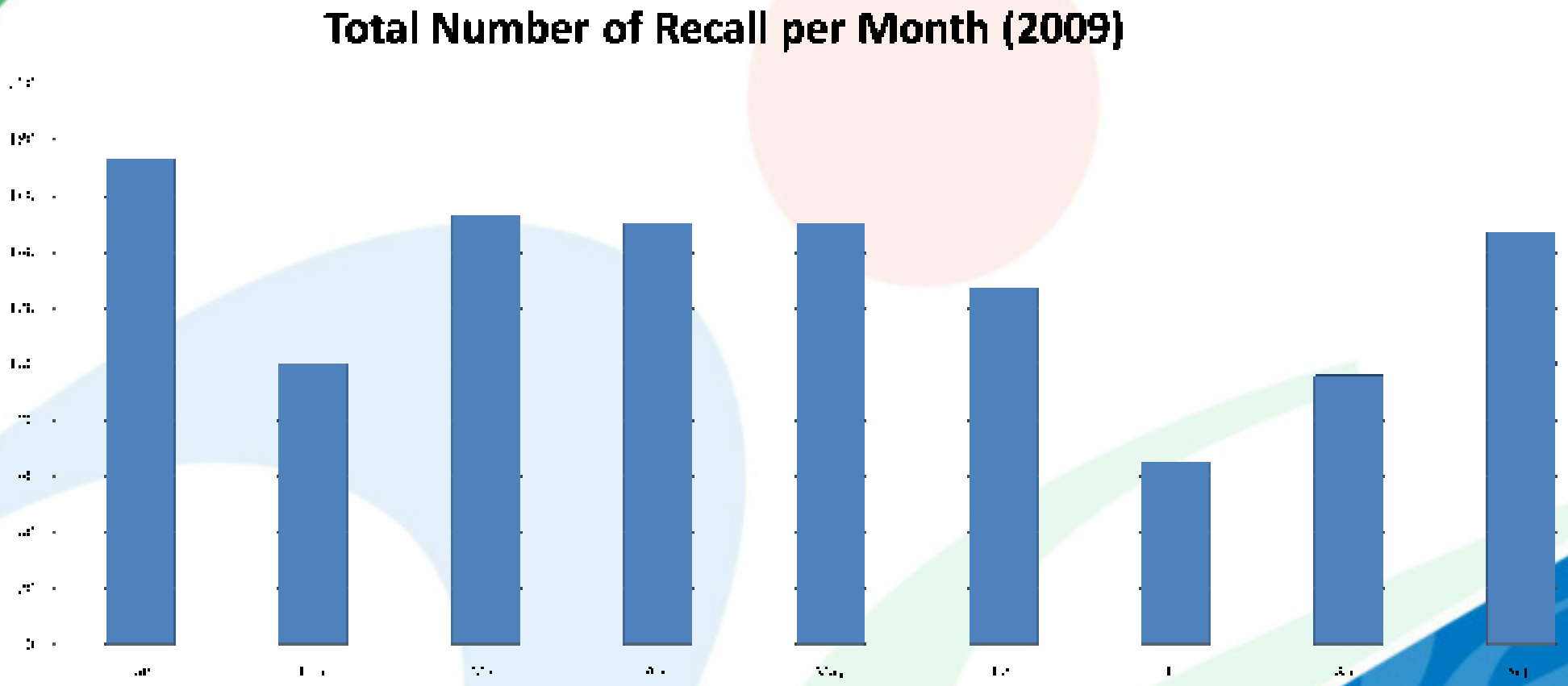
National Center For Medical Device Reporting (NCMDR) (cont)



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Medical Devices Data Bases (MDDB)

- **The Medical Devices DATA Base (MDDB) consists of six highly specialized databases that contain valuable information related to Medical Devices offered in cooperation with the Emergency care research institute (ECRI).**

- **The MDS is working on setting up A National center for medical devices information (NCMDI) that contain these data bases and more.**

International Achievements

Medical Devices Sector is a member of :

- ✓ **AHWP**
- ✓ **Vice chair of AHWP Technical Group.**
- ✓ **AHWP working groups**
  - **Pre- Market (WG1).**
  - **Post Market (WG2).**
  - **Quality Management (WG3).**
- ✓ **The GHTF study group 3 (SG3) Quality systems**

On Going Projects

- **Medical devices regulatory system.**
- **Medical Devices Licensing System (MDL).**
- **Evaluation of the MD/IVD market in Saudi Arabia.**
- **Contracting Conformity Assessment Bodies (CAB's) for Pre-Market.**

ترخيص الأجهزة الطبية
MDL
Medical Devices Licensing

On Going Projects (cont)

- **Medical devices Unique Identification and Interfacing with Hospitals.**
- **Evaluation of optometry facilities in Saudi Arabia.**
- **Evaluation of the current practice Pertaining to Single Use Devices.**
- **Sale of used Medical Devices.**

Thank You

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