Overview of Medical Devices Sector Saudi Food and Drug Authority (Saudi Arabia)

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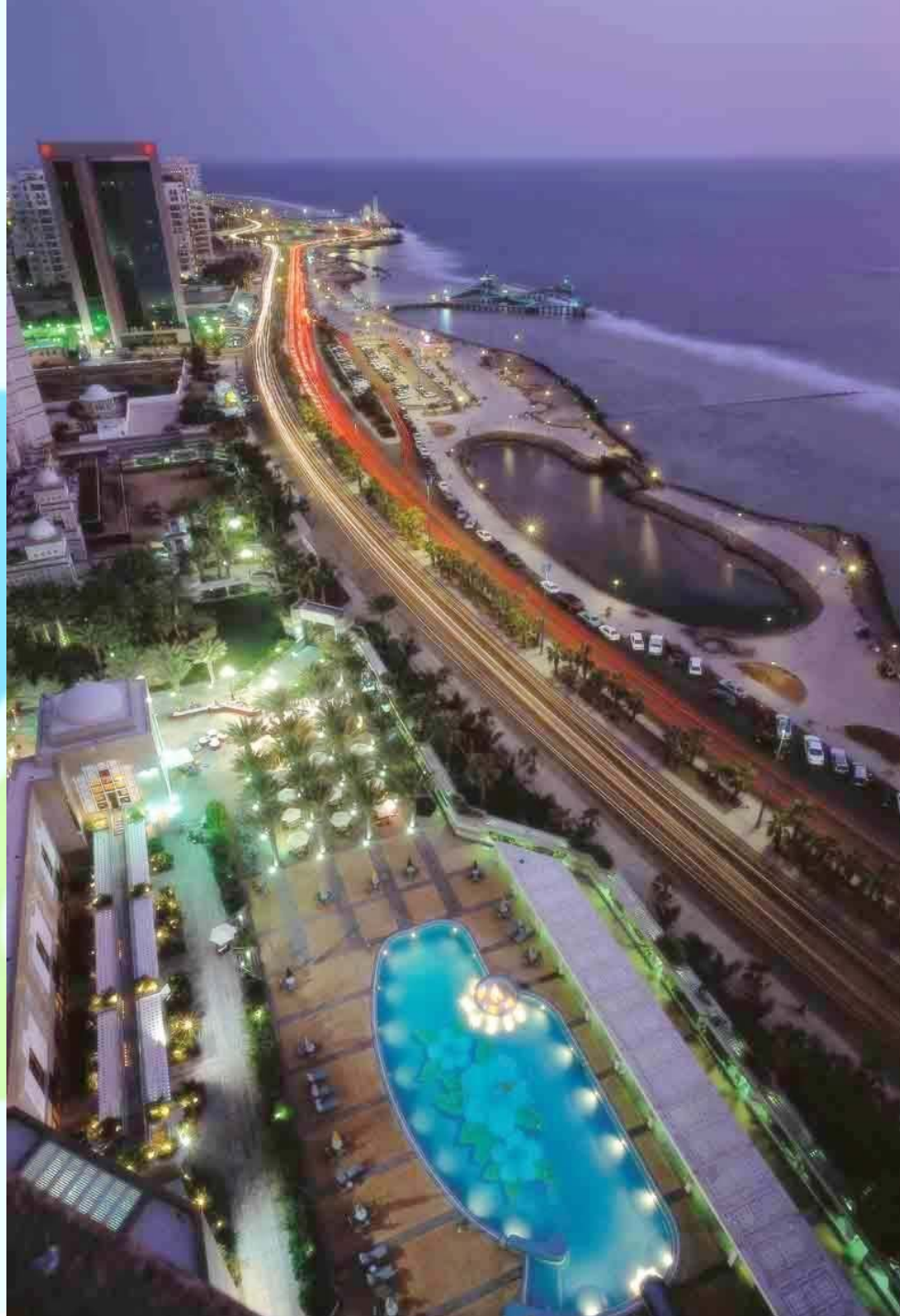

Presentation Content

- Introduction
- Medical Devices Sector Objectives
- MD/IVD market in Saudi Arabia
- On going projects
- Future projects

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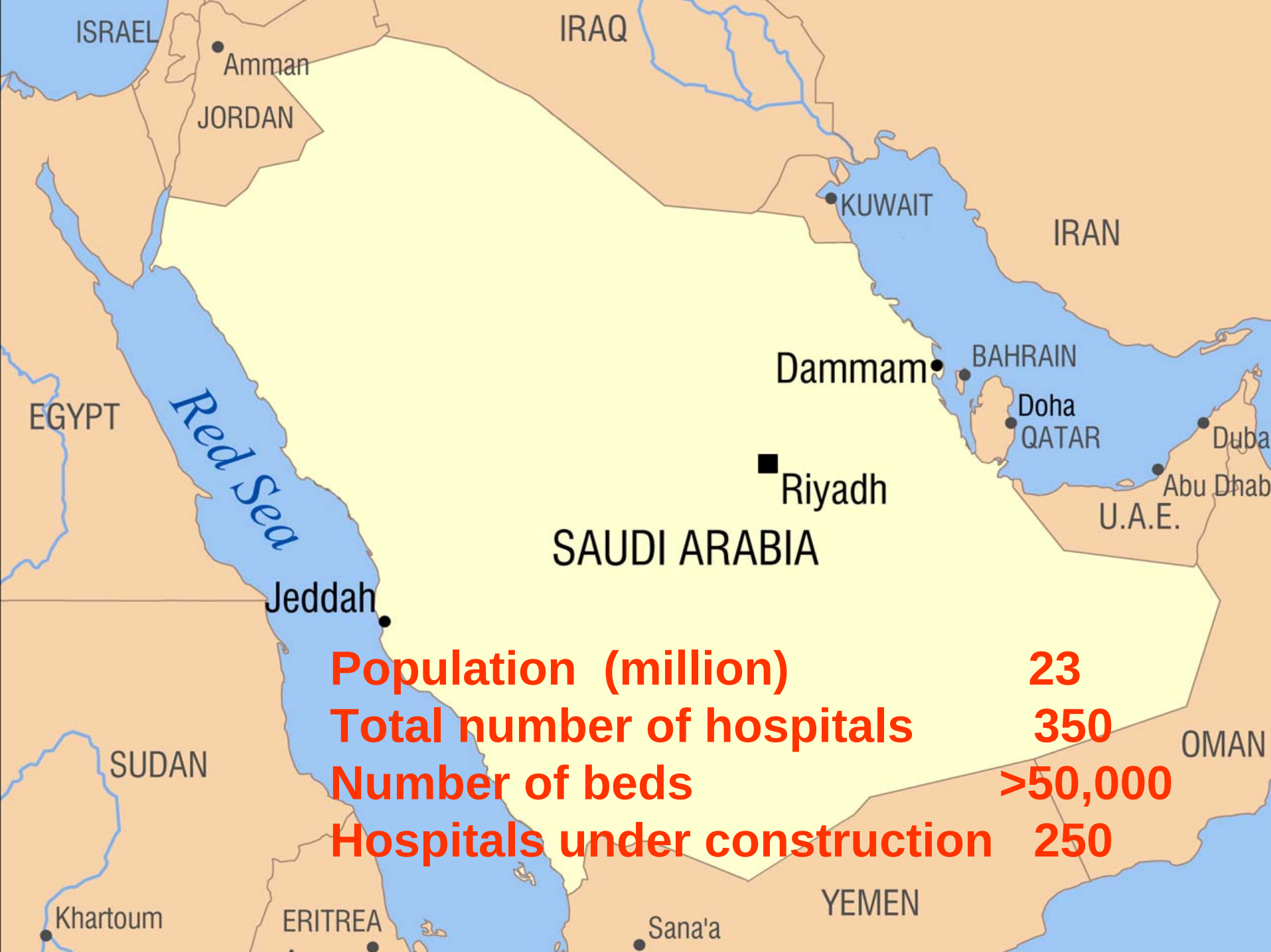
ISRAEL
Amman
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IRAQ
KUWAIT
IRAN
Dammam
BAHRAIN
Doha
QATAR
Duba
Abu Dhab
U.A.E.
EGYPT
Red Sea
Riyadh
SAUDI ARABIA
Jeddah
SUDAN
OMAN
YEMEN
Khartoum
ERITREA
Sana'a
Population (million) 23
Total number of hospitals 350
Number of beds >50,000
Hospitals under construction 250

Introduction

- **The Saudi Food & Drug Authority (SFDA) was established on March 10, 2003.**
- **A royal decree was issued on Feb. 13, 2007 to establish the law of SFDA.**
- **A council of ministers decision was issued on June 18, 2007 giving the SFDA a full authority to regulate the medical device market in Saudi Arabia.**
- **SFDA is an independent body with an independent budget.**
- **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

Vision

To be the leading regional regulatory authority for Food, Drug, and Medical Devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.

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Introduction (cont)

SFDA

Mission

To ensure the safety of Food; the safety, quality and efficacy of Drug; and the safety and effectiveness of Medical Devices, by developing and enforcing an appropriate regulatory system.

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Saudi Food & Drug Authority

Introduction (cont)

- **The Medical Devices Sector in the Saudi Food and Drug Authority is in charge of Regulating:**

  - **Medical Devices.**
  - **IVD devices.**
  - **Prescription eye glasses.**
  - **Contact lenses and their solutions.**
  - **Electronic products related to public health.**

Introduction (cont)

MDS

Vision

To be a regionally distinguished regulatory authority for medical devices and related electronic products, working toward safeguarding the public health of Saudi Arabia

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Saudi Food & Drug Authority

Introduction (cont)

MDS

Mission

To ensure safety, efficacy, and quality of medical devices and their performance according to their intended purpose, and to ensure the safety of related electronic products

Objectives

The Medical Devices Sector is working toward becoming the leading regulatory authority in GCC through achieving short and long term objectives. Among which are:

Objectives (cont)

Setting up Medical devices & IVD regulatory law.

Implementing rules and quality standards

Objectives (cont)

Implementing regulatory system

Surveillance and monitoring of the market

Objectives (cont)

Setting up licensing procedures for medical devices manufacturers and suppliers

Objectives (cont)

Establishing good communication and cooperation through MOU'S with other regulatory authorities

MD/IVD Market in Saudi Arabia

There is insufficient information on the market size and the range of MD/IVD products sold and used in SA.

MD/IVD Market in Saudi Arabia (cont)

- SA relies heavily on import of medical devices to satisfy country needs.
- MD establishments in SA consist mainly of importers and distributors, with relatively few manufacturers.
- Major local manufacturers produce mostly class I MD.

On going projects

- Medical Devices National Registry (**MDNR**).
- Medical devices regulatory system.
- Medical devices Interim market access measures.
- Medical Devices Problem Reporting System (MDPR).
- Evaluation of the MD/IVD market in Saudi Arabia.

Medical Devices National Registry (MDNR)

- **MDNR** is a web based enrollment scheme for MD establishments, manufacturers, agents and suppliers in SA and their product.

Medical Devices National Registry (MDNR) (cont)

Objective:

- To establish a database of all establishments, manufacturers, agents and suppliers working in the field of medical devices, IVD, prescription eye glasses, and contact lenses, as well as , their product.

- To measure the readiness of medical devices establishments to comply with medical devices regulations.

Medical Devices National Registry (MDNR) (cont)

MID NOVEMBER 2007

The registry system will be launched during 3 workshops in 3 major cities.

Medical Devices Regulatory System.

Main Objective

Lay out the strategic directions of a multi-year work program to develop an appropriate roadmap for MD regulatory framework in cooperation with the WB. It involves recruitment of experts to:

Medical Devices Regulatory System (cont)

- Prepare a comprehensive medical devices regulatory system.
- Develop framework legislation and implementing rules.
- Adopt appropriate "recognized standards"

Medical Devices Regulatory System (cont)

- Set up an “interim” market access measures.
- Prepare regulation for health facilities.

Medical Devices Regulatory System (cont)

"Interim" Market Access Measures

- SFDA will adopt a regulatory system which complies with GHTF guidance.
- Devices must comply with regulations of one of the 5 GHTF founding members
- SFDA may impose country specific provisions.

Medical Devices Regulatory System(cont)

Health Facilities Regulation.

- Incident Analysis
- Adverse event reporting.
- Installation and maintenance of devices.
- Appropriate use of devices.
- New technologies in health care.


ترحب
الغرفة التجارية الصناعية بالرياض
بالسادة حضور ورشة عمل حول
وضع مسودة العناصر الأولية لنظام [illegible] والمنتجات الطبية
برعاية [illegible] الدواء
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
Medical Devices Sector
Vision
To be a regionally distinguished regulatory authority for medical devices and [illegible] electronic products, working to safeguarding the public health Saudi Arabia
Mission
To ensure safety, efficacy [illegible] medical devices and the [illegible] according [illegible] their
JOS PUTZEYS
SENIOR MANAYER OF JKN CONSULT
DR. MICHAEL CHENG
INTERNATIONAL CONSULTANT

Medical Devices Problem Reporting System (MDPR)

This project is carried out in cooperation with ECRI. Its main objectives are:

- To launch a fully functional web-based problem reporting system to collect reports from manufacturers, hospitals & other healthcare providers.
- Assisting the MDS in the implementation of the system
- Training MDS personnel on reporting and accident investigation.


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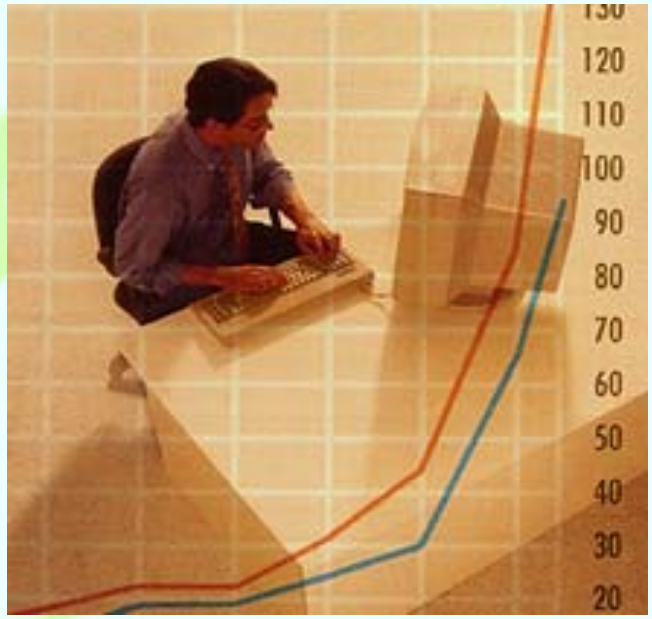
SFDA

Evaluation of the MD/IVD Market in Saudi Arabia.

Currently there is an on going project to evaluate MD/IVD market in Saudi Arabia



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Future Projects

Among the main projects for year 2008:

- Designate CAB's for pre-market
- Registration System
- Reference Laboratories
- Technical support for healthcare facilities
- Twining with other regulatory authorities.
- Setting up the requirements for MD control at port of entry.

MDS believes in Harmonizing

- Standards
- Conformity Requirements
- Approval; Certification Requirements

GHTF

AHWP

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Thank you

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