Brief overview of SFDA registration process for medical devices

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Kingdom of Saudi Arabia (KSA)

- Population: 28,160,273 (July 2016 est.)
- GDP $637.8 billion (2015 est.)
- Very wealthy market
- Heavily reliant on medical imports (makes up over 90% of the medical device market)
- Government is seeking to expand the role of the private sector in healthcare
Kingdom of Saudi Arabia (KSA)

Medical Products

- Cumulative spending from 2015-2019 ($14 Billion)
- Annual spending on capital equipment ($1.2 Billion)
- Annual spending on consumables ($400 Million)
- Annual spending on patient aids ($190 Million)
KSA Market Entry Topics

- Reference market approval required
- Assign local Authorized Representative (AR)
- Submit application for Conformity Assessment Body (CAB) and SFDA review
- Select Distributor
- Approval in 3-6 months
Cargo
• Shipment arrives at port
• Broker sends release request to customs

Saudi Customs
• Verifies shipment and documents
• Request clearance from SFDA

SFDA
• Documents review
• Physical check of shipment contents
• Issue clearance letter or notes
# Medical Device Shipments Statistics

## Cleared Medical Device and IVD Shipments

<table>
<thead>
<tr>
<th>Year</th>
<th>Value of cleared items</th>
<th>Quantity of cleared items</th>
<th>Number of cleared items</th>
<th>Number of cleared Shipments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>3,811,895,770</td>
<td>706,898,114</td>
<td>20,924</td>
<td>9,654</td>
</tr>
<tr>
<td>2012</td>
<td>3,971,027,439</td>
<td>553,716,312</td>
<td>22,578</td>
<td>10,953</td>
</tr>
<tr>
<td>2013</td>
<td>5,943,011,354.30</td>
<td>1,386,694,869.23</td>
<td>28,942</td>
<td>14,510</td>
</tr>
<tr>
<td>2014</td>
<td>6,382,906,129.50</td>
<td>1,475,562,923.90</td>
<td>35,732</td>
<td>16,043</td>
</tr>
<tr>
<td>2015</td>
<td>7,847,624,769.52</td>
<td>2,496,649,511</td>
<td>26,997</td>
<td>17,974</td>
</tr>
</tbody>
</table>

## Rejected Medical Device and IVD Shipments

<table>
<thead>
<tr>
<th>Year</th>
<th>Value of rejected items</th>
<th>Quantity of rejected items</th>
<th>rejected Items</th>
<th>rejected Shipments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>24,519,744</td>
<td>3,014,176</td>
<td>2921</td>
<td>458</td>
</tr>
<tr>
<td>2012</td>
<td>104,000,605</td>
<td>39,652,279</td>
<td>6,043</td>
<td>750</td>
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<tr>
<td>2013</td>
<td>66,574,325.09</td>
<td>5,739,831</td>
<td>4,815</td>
<td>633</td>
</tr>
<tr>
<td>2014</td>
<td>87,587,056.63</td>
<td>12,791,982</td>
<td>7,169</td>
<td>798</td>
</tr>
<tr>
<td>2015</td>
<td>60,559,967</td>
<td>4,636,723</td>
<td>4,149</td>
<td>673</td>
</tr>
</tbody>
</table>
Questions?
Thank you very much for your time and attention

My contact information:
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Our Areas of Expertise
- Classification & RA Strategy
- Device/IVD Registration
- In-Country Representation
- Internal/Supplier QMS Audits
- ISO 13485:2016 Transition
- EU MDR/IVDR Compliance
- Clinical Consulting Support
The KSA Healthcare Sector and Vision 2030
Briefing

February 2017
The Kingdom faces several healthcare challenges

- **Primary care** lacks capacity and quality so urban tertiary care is flooded with patients.
- **High obesity and diabetes** rates deteriorate overall health of the population.
- **High fragmentation** leads to siloed approach rather than integrated care.
- **Emergency room wait time** often exceeds four hours.
- **Current data sources** do not give a complete picture of outcomes and costs.
- **Training programs** do not graduate enough doctors and nurses to address the healthcare needs of Saudi citizens.
The three pillars of Saudi Arabia's Vision 2030 will drive the evolution of Saudi healthcare

A Vibrant Society
- With strong toots
- With fulfilling lives
- With strong foundations

A Thriving Economy
- Rewarding opportunities
- Open for business
- Investing for the long term
- Leveraging its unique position

An Ambitious Nation
- Effectively governed
- Responsibly enabled

What type of care is necessary to support a growing Saudi population?

How can the healthcare sector contribute to the diversification of the Saudi economy?

How can the government and non-profit sectors better collaborate to deliver quality healthcare?
The Vision mentions specific tasks the Kingdom can do to enhance the quality of care...

"A healthy and balanced lifestyle is an essential mainstay of a high quality of life"

- Promote preventative care
- Integrate health and social care
- Address mental health
- Better caregiver training
- Ensure sustainable funding
- Address chronic diseases
- Establish transparency among providers
- Reduce wait times
...and several systemic shifts that will support the activation of these tasks

- Introduce **corporatization** to enhance capability and efficiency
- Utilize **privatization** to open up new investment and spur innovation
- Encourage adoption of technology to improve accessibility, efficiency and transparency
- Develop **NGOs** to supplement government support
MOH reflects the vision of health care in its transformation priorities

- Set up National Health Insurance
- Receive funding from additional resources

- Increase private sector participation (from <20% to >40% in next 5 years)
- Support localization of pharma and medical devices

- Provide tools for patient self service, prevention, connected care
- Accelerate IT infrastructure development

- Focus on prevention and build primary care
- Emphasis on out-of-hospital care models
- Develop care provisioning across all sectors

- Enhance quality of workforce
- Establish healthcare workforce planning

- Split MOH, corporatize delivery and create independent provider network
- Strengthen mandate to lead reform

Source: MOH

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Saudi Arabia's Healthcare Landscape

Arab Health - United States Embassy, Dubai

1 February 2017
Part 1
An Overview of Dentons
About Us - Dentons

• Dentons was formed in March 2013 with the combination of international law firms SNR Denton and Salans LLP along with Canadian law firm Fraser Milner Casgrain LLP.

• Dentons is truly a global law firm:
  • More than 6,500 lawyers and professionals
  • 140 offices worldwide
  • 57 different countries across Africa, Asia Pacific, Canada, Central Asia, Europe, the Middle East, Russia & the CIS, the UK, and the US.
An Unrivalled Middle East Network

- Our Middle East practice is particularly strong.
- We have been on the ground in the Middle East since 1964.
- We have offices in seven different countries across the Middle East.

Active in region since the 1930s
In Cairo since 1964
9 offices in 7 countries
110+ lawyers
30+ bilingual Arabic and English speakers
Full suite of practice and sector expertise

We offer high quality, specialist advice and representation to foreign entities doing business in Saudi Arabia in all relevant areas.

Key Practices

- Commercial / Corporate Law
- Healthcare Products
- Dispute Resolution
- Employment Law
- Energy & Projects
- Finance
- Intellectual Property & Data Protection
- International Law
- Real Estate

- Environment & Natural Resources
- Government Investigations
- Public Policy & Regulation
- Venture Technology & Emerging Growth Companies
Part 2
Overview of Saudi Arabian Healthcare Market - Rules and Regulations
Relevant Executive Agencies

The two main executive agencies responsible for healthcare in the Kingdom are as follow:

1. **Ministry of Health (MoH):** The MoH is the highest-level supervisory board that oversees all aspects of the Kingdom's healthcare services, and is responsible for building hospitals & healthcare centers, as well as issuing and enforcing regulations for the practice of medicine and pharmacology.

2. **Saudi Arabian Food & Drug Authority (SFDA):** The SFDA was established by the Council of Ministers (CoM), as an independent authority reporting to the CoM. The SFDA aims to "ensure the safety of food, safety, quality, and effectiveness of drugs, and the safety, quality, efficacy, and performance of medical devices ..."
Overview of Saudi Arabian Healthcare Market

The following areas address the general system of healthcare law that applies in Saudi Arabia

• Product approval
  • SFDA (for Saudi Arabia only)
  • GCC Secretariat General of Health (for GCC-wide distribution)

• SFDA regulations sectors
  • Medical Devices Branch
  • Drugs Branch
  • Foods Branch

• SFDA scope of authority
  • Enforcement of existing Health Laws
  • Promulgation of New Rules and Regulations
  • Licensing
  • Supervision and Inspection
  • Consumer Protection
Best Practices & Typical issues in the Saudi Healthcare Market

Entrance into the Saudi Arabian healthcare market is best seen as a choice between two options:

1. **Incorporation** of New Entities

2. **Agency Agreements** with Existing Saudi Entities
Option 1: Incorporation

It is theoretically possible for a foreign healthcare manufacturer to establish a corporate presence in Saudi Arabia, but two significant hurdles make it a highly uncommon occurrence.

1. Foreign Investment Hurdles
   - Saudi Arabian General Investment Authority (SAGIA): Obtaining a foreign investment license from SAGIA requires significant investment.
   - Protectionism: Distribution companies were formerly required to have minimum 25% Saudi-owned, but 100% foreign-owned entities are now a possibility with more stringent investment requirements.

2. Regulatory Hurdles
   - The Ministry of Health (MoH): The MoH grants licenses to foreign healthcare manufacturers on a case by case basis.
Option 2: Agency

The sale of a foreign healthcare manufacturer’s products in Saudi Arabia most often occurs through a commercial agency (distribution) arrangement.

- Commercial Agency Law and Implementing Regulations
  - Regulates the relationship between the foreign principal and the Saudi agent
  - Registration and deregistration issues / assessment of fees.
  - Termination of Distributorship / indemnity payments
Option 2: Agency (Continued)

• SFDA regulations
  • Medical devices
    • SFDA regulations require an Authorized Representative (AR) to list medical devices and to obtain their approval for sale in Saudi Arabia.
    • The AR must be licensed and established in Saudi Arabia and becomes liable for penalties and damages for faulty products.
    • Generally, the Saudi agent will act as the AR, but it is not strictly required.

• Drugs
  • Drugs do not require an AR, but in order to sell them on the Saudi market they must be either:
    1. Listed: if it is a low risk product such as dietary supplements, cosmetics, and the like; or
    2. Registered: if it is not a low risk health product.
  • Although it is not strictly required, generally the Saudi agent will handle all listing / registration issues.
Part 3
Available Business Structures in Saudi Arabia
Saudi Arabian General Investment Authority

The **Saudi Arabian General Investment Authority (SAGIA)** regulates all foreign investment in Saudi Arabia under the **Foreign Investment Law**.

- The most common—and in many instances *only*—structures available to a foreign entity seeking to establish a registered presence in Saudi Arabia are:
  1. **Limited Liability Company**
  2. **Branch Office of the Foreign Entity**
Limited Liability Company: Overview

- **General Purpose:** Traditionally the LLC structure was most often used when a foreign company has decided to operate in the private sector or for an extended period with a Saudi Arabian partner.

- **Term:** Established for a specified number of years as determined by the shareholders, with an option for renewal of the term (e.g., 50 years)

- **Legal Abilities:**
  - May bid on and perform private and public sector projects in the Kingdom.
  - May sponsor residency and work permits (iqama) for its employees.

- **Liability:** Shareholders’ liability generally limited to their capital contributions to the LLC (Exceptions for fraud, *inter alia*)

- **Minimum Saudi Arabian Participation:** None. SAGIA will permit a 100% foreign-owned LLC to be established by a single shareholder, but distribution with a Saudi partner is still an option (as discussed *infra*).
Branch Office: Overview

• **General:** Branch offices are not specifically provided for in the Companies Law.

• **Term:** License will **not** expire upon completion of a particular public sector project (unlike a temporary commercial registration).

• **Legal Abilities:** In practice, foreign companies are permitted to establish branch offices, which have been **authorized as a matter of government policy.**
  
  • Offers a foreign company a **great deal of flexibility** in the role it can play, whether in respect of actual projects or support to other entities, including agents and distributors.
  
  • Provides **technical assistance and training** to distributors.
  
  • Like an LLC, a branch office **may sponsor own employees.**

• **Liability:** Attributable back to the parent entity.

• **Minimum Saudi Arabian Participation:** None. Serves as an independent entity in Saudi Arabia with no particular commitment to any Saudi party.
Capitalization (LLC and Branch)

Capitalization requirement:

• Minimum Capital by type of activity
  • SAR 500,000 (USD 133,333.33) for services entity
  • SAR 1,000,000 (USD 266,666.66) for a manufacturing entity,
  • SAR 26,666,667 (USD 7.1 million) for a distribution entity.
• The minimum capital for a wholly owned distribution entity is SAR 30 million (USD 8 million).
  • commit to a substantial invest of a minimum SAR 200 million (~USD 53.3 million) in the first five (5) years after establishing the entity.
• Final amount will be determined in consultation with SAGIA based on the specific details of the proposed investment/operations.
Considerations:

- **Activities**: Careful consideration should be given to the authorized activities.
  - **Doctrine of ultra vires** is alive and well in Saudi Arabia.
  - Companies will be legally restricted to performing only those activities listed in the Articles of Incorporation.
Part 4
Establishing a Presence in Saudi Arabia
Establishing an LLC in Saudi Arabia

• Applicable Laws:
  • Companies Law and Implementing Regulations (Companies Regulations)
  • Foreign Investment Regulation (Investment Regulations)

• The Process:
  1. File application for Foreign Investment License with SAGIA.
  2. Obtain approval of foreign investment license.
  3. Enter into Joint Venture Shareholder's Agreement (JVA), if more than one shareholder.
  4. Prepare and submit Articles of Association (AoA) to Ministry of Commerce and Investment (MoCI).
  5. Synopsis of AoA submitted to Official Gazette for publication.
  6. Deposit required paid-up capital to an in-Kingdom bank and obtain certificate.
  7. MOCI issues Commercial Registration certificate (CR).
A Legal Guide to Doing Business in Saudi Arabia

• The essential guide for companies doing business in Saudi Arabia.
• By Amgad Husein and John Balouziyeh (Dentons, Riyadh).
• Published by Thomson Reuters.
• Available at www.sweetandmaxwell.co.uk
Part 5
Question and Answer Section
Your Presenters

Amgad Husein, Partner, Riyadh

Having practised in the Middle East since 1999 and in Riyadh since 2001, Amgad's work focuses primarily on major American, European and Asian banking and industrial and corporate institutions doing business in the Kingdom of Saudi Arabia. Chambers Global notes that clients praise the Riyadh group's "helpfulness, efficiency and in-depth knowledge of local and international law" and that Amgad Husein "consistently impresses with his advice and assistance." Clients are full of praise for Amgad Husein, with one saying: "much of the value comes from Amgad. He rolls up his sleeves and gives good, helpful advice. He is dedicated and always on call." Amgad is recommended for his “practical approach and very good understanding of the Saudi commercial and governmental environment.”

Anas Akel, Partner, Jeddah

Anas Akel is a Partner in Dentons' Saudi Arabia Practice and is based in Jeddah. He advises companies and foreign investors in setting up and operating in Saudi Arabia and has handled a wide array of corporate, commercial and cross-border transactions in the United States, Latin America, Asia, and the Middle East. His background includes representation on regulatory compliance, insurance and capital markets matters. Prior to joining the firm, Anas was the General Counsel and Corporate Secretary of AlAhli Takaful Company (ATC), a publicly listed insurance company in the Kingdom of Saudi Arabia, where he was responsible for legal, compliance and regulatory matters. Anas is fluent in Arabic and English and proficient in Spanish.

Kelly Tymburski, Partner, Dubai

Kelly is based in our Dubai office. She has significant expertise and experience advising on both projects/commercial and regulatory matters, having been based in the Middle East since 2007. Kelly has a significant breadth and depth of experience supporting clients in the region, both in a private practice advisory capacity and also in-house during various secondment experiences. Her advice is therefore both legally sound and commercially practical.